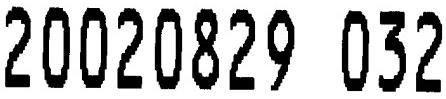


REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.</p>			
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED	
	15.Jul.02	THESIS	
4. TITLE AND SUBTITLE		5. FUNDING NUMBERS	
THE HIPAA PRIVACY RULE'S IMPACT ON THE COST, ACCESS, AND QUALITY OF HEALTH CARE			
6. AUTHOR(S)			
MAJ TRIPP CHARLES H			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)		8. PERFORMING ORGANIZATION REPORT NUMBER	
SETON HALL UNIVERSITY		CI02-156	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)		10. SPONSORING/MONITORING AGENCY REPORT NUMBER	
THE DEPARTMENT OF THE AIR FORCE AFIT/CIA, BLDG 125 2950 P STREET WPAFB OH 45433			
11. SUPPLEMENTARY NOTES			
12a. DISTRIBUTION AVAILABILITY STATEMENT		12b. DISTRIBUTION CODE	
Unlimited distribution In Accordance With AFI 35-205/AFIT Sup 1			
13. ABSTRACT (Maximum 200 words)			
DISTRIBUTION STATEMENT A Approved for Public Release Distribution Unlimited			
14. SUBJECT TERMS			15. NUMBER OF PAGES
			66
			16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

Chuck Tripp

THESIS TOPIC:
THE HIPAA PRIVACY RULE'S IMPACT
ON THE COST, ACCESS AND QUALITY OF HEALTH CARE

Congress recognized the need for national patient record privacy standards in 1996 when they enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA). While the law included provisions designed to save money for health care businesses by encouraging electronic transactions, it also required new safeguards to protect the security and confidentiality of that information. The law gave Congress until August 21, 1999 to pass comprehensive health privacy legislation. When that did not happen, the law required the Department of Health and Human Services (HHS) to craft such protections by regulation - The Privacy Rule. The initial proposed regulations were published in November 1999 and attracted over 52,000 comments. The final rule was published in December 2000 with an effective date of April 14, 2001. As required by law most covered entities have two years - until April 14, 2003 to comply with the final rule's provisions.

The Final Privacy Rule applies to health plans, health care clearinghouses, and those health care providers who transmit any health information electronically. The main provisions of the "Rule" are: Consent (45 CFR § 164.506), the Minimum Necessary Standard (45 CFR §§ 164.502(b), 164.514(d)), Business Associates (45 CFR §§ 160.103, 1164.502(e), 164.514(e)), Marketing (45 CFR §§ 164.501, 164.514(e)), and Government Access to Health Information (45 CFR §§ 160.300, 164.512(b), 164.512(f)). For the

purposes of my paper, I will focus on the Consent and Minimum Necessary Standard provisions because they appear to have the greatest potential impact on the cost, access, and quality of health care.

The consent requirement provides that a covered health care provider must obtain the individual's consent prior to using or disclosing protected health information to carry out treatment, payment, or health care operations. However, consent is not required for providers who have an indirect treatment relationship such as a radiologist. Further, a provider may forgo prior consent when providing emergency treatment, when required by law to treat the individual, and the provider is unable to obtain such consent, or in instances of severe communications barriers where the provider in exercising his professional judgment finds that the individual's consent is inferred. The regulation allows a covered health care provider to condition treatment on the provision of the individual's consent. It further allows the individual to revoke his/her consent, except to the extent that the covered entity has taken action in reliance of it.

The consent requirement has engendered a fair amount of concern from a variety of interested parties as evidenced in my review of testimonies before the National Committee on Vital and health Statistics Subcommittee on Privacy and Confidentiality. Two representative entities are Kaiser Permanente and the American Pharmaceutical Association. A spokesperson for Kaiser Permanente stated that the consent requirement would create unintended but significant barriers to the delivery of health care services to their 8.2 million members. She emphasized the administrative burden of obtaining the consents as well as the life threatening implications of not having the consent in place. She further stated that an additional concern of theirs is that because the regulation allows

health care providers to condition treatment on the provision of the individual's consent, the consent does not provide patients a truly informed and voluntary choice. A spokesperson for the American Pharmaceutical Association stated that the prior consent requirement erects significant barriers to the quick, efficient, and safe delivery of health care that patients count on pharmacists to provide. Pharmacies will have to have consent forms in hand before they are allowed to dispense needed medications. Perhaps a greater concern appears in the event of a needed recall of a medication. Pharmacists are concerned with what would happen in that situation for people who have either not submitted consent or have revoked their consent.

The minimum necessary standard requires a covered entity to make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. This requirement does not apply to disclosures to or requests by a health care provider for treatment, disclosures to the individual who is the subject of the information, disclosures made to the Secretary of Health and Human Services, and uses or disclosures that are required by law. For routine and recurring disclosures of protected health information, the covered entity must implement policies and procedures that limit the protected health information to the amount reasonably necessary to achieve the purpose of the disclosure. For non-recurring disclosures, the covered entity must develop criteria to limit the protected health information being disclosed, and review requests for disclosure on an individual basis in accordance with such criteria. The regulation further provides that a covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when the request is made by a public

official, another covered entity, a professional who is a workforce member or business associate of the covered entity holding the information, or a researcher with appropriate documentation from an Institutional Review Board (IRB) or Privacy Board.

The minimum necessary standard has also stimulated concern. A spokesperson for the Health Insurance Association of America (HIAA) testifying before the National Committee on Vital and health Statistics Subcommittee on Privacy and Confidentiality, stated, "Because the minimum necessary standard is inherently vague, we are concerned that it will lead to "defensive" restrictions on the flow of information between providers and health plans due to fears about the legal risk of disclosing information. We believe this may have negative consequences for the quality and affordability of health care." He stated, additionally, that the minimum necessary standard will be very costly to implement, up to \$19.8 billion over five years for hospitals alone. A spokesperson for the American Association of Health Plans (AAHP), also testifying before the subcommittee, stated, "If the privacy rule is at all vague or ambiguous about what a health plan may do, the plaintiff's bar will use it as a weapon." He recommended that HHS clarify the guidance to say that the standard is satisfied so long as the covered entity reasonably believes that the information is necessary to perform the task at hand.

The privacy rule, while it is a final rule, is subject to modification. Based on my research to date, I expect that modifications are imminent. A noted aim of HHS is that the privacy protections not interfere with a patient's access to or the quality of health care delivery. My paper, while focusing on the above two provisions of the Privacy Rule, will analyze the concerns of interested parties, measure them against the actual provisions in the regulation, and will propose a means of implementing the rule that will best protect

the individually identifiable health information while minimizing its impact on the cost, access and quality of health care.

THESIS
Chuck Tripp
15 Nov 01

**THE HIPAA PRIVACY RULE'S IMPACT
ON THE COST, ACCESS, AND QUALITY OF HEALTH CARE**

I. INTRODUCTION:

Congress recognized the need for national patient record privacy standards in 1996 when they enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA). While the law included provisions designed to save money for health care businesses by encouraging electronic transactions, it also required new safeguards to protect the security and confidentiality of that information. The law gave Congress until August 21, 1999 to pass comprehensive health privacy legislation. When that did not happen, the law required the Department of Health and Human Services (HHS) to craft such protections by regulation - The Privacy Rule. The initial proposed regulations were published in November 1999 and attracted over 52,000 comments. The final rule was published in December 2000 with an effective date of April 14, 2001. As required by law most covered entities have two years - until April 14, 2003 to comply with the final rule's provisions.

The Privacy Rule has engendered a great deal of response from the health care community, as evidenced by the 52,000 comments mentioned above. Seemingly, every part of the community from health care providers, insurers, pharmacists, to health-related advocacy groups have voiced both support and concern over the then proposed Privacy Rule. This paper will first analyze the Privacy Rule, discussing the make-up of the regulation, defining the "words of art" terms, and reviewing the proposed benefits and costs associated with the implementation of the Rule. The paper will then focus on three key aspects of the Rule that appear to have the greatest potential affect on the cost, access, and quality of care - 1) the Consent Requirement, 2) the Minimum Necessary Requirement, and 3) the lack of Federal Preemption. In discussing these three aspects of the Rule, I will discuss the concerns voiced by the various segments of the health care community, and their recommendations for making the Rule easier to live with while maintaining its overarching purpose of protecting personal health information. The paper will then briefly discuss the ongoing proposed modifications to the Rule, based on the voiced concerns. Finally, I will propose my recommendations for implementation of the Rule - that will aim to maximize the goal of the Rule, while minimizing the associated effects on the costs, access, and quality of care.

II. THE PRIVACY RULE:

The goal of the Privacy Rule is to protect individuals' rights to privacy in matters involving their health care. It stems from a concern that if individuals are worried about the privacy of their health care information, they may withhold important information from their health care providers which may be necessary for their care. *Complex Privacy Regulations Have Far Reaching Impact*, 13 Health Lawyer 1, April 2001 (#24) It has also been noted that in order to protect their privacy and avoid embarrassment, stigma and discrimination, individuals have withheld information from their health care providers, provided inaccurate information, paid out of pocket for care that is covered by insurance and, in some instances, avoided care altogether - The Privacy Rule was promulgated to create a uniform, strong national standard to allay the concern of health care consumers (patients). *Frequently Asked Questions about HIPAA*, <http://www.hipaantidote.com/faq.asp> (#3)

The Privacy Rule is the first comprehensive federal protection for privacy of health care information. *Standards for Privacy of Individually Identifiable Health Information*, Office of Civil Rights, <http://aspe.os.dhhs.gov/admnsimp/final/pvcguide1.htm> (#6)

Because of its federal reach, the Privacy Rule establishes a threshold that must be met in every jurisdiction. John Kelley, *HIPAA Privacy Rule Guidelines*, *The Internet Law Journal*, <http://www.tilj.com/content/healtharticle09040101.htm> (#42)

The Privacy Rule applies only to covered entities - health plans, health care clearinghouses, and health care providers who transmit certain health information electronically. 45 CFR § 160.502. The focal point of the privacy rule is the general prohibition on the dissemination of personal health care information. The rule states that "a covered entity may not use or disclose protected health information except as permitted or required" by the rule. 45 CFR § 164.502.

The main provisions of the "Rule" are: Consent (45 CFR § 164.506), the Minimum Necessary Standard (45 CFR §§ 164.502(b), 164.514(d)), Business Associates (45 CFR §§ 160.103, 1164.502(e), 164.514(e)), Marketing (45 CFR §§ 164.501, 164.514(e)), Government Access to Health Information (45 CFR §§ 160.300, 164.512(b), 164.512(f), and Preemption (45 CFR, Subpart B).

A. DEFINITION OF KEY TERMS

In this section I will provide the definitions of key terms in the rule - Definitions are found in the regulations at 45 CFR §§ 160.103, 160.202, and 164.501.

45 CFR § 160.103 definitions: Business Associate, Compliance Date, Covered entity, Health Care, Health care clearinghouse, and Health information, Health Plan.

45 CFR § 160.202 definitions: Contrary, and More stringent.

45 CFR § 164.501 definitions: Disclosure, Indirect treatment relationship, Individually identifiable health information, Law enforcement official, Marketing, Payment, Protected health information, Treatment, and Use.

These selected definitions are critical in the understanding of the Privacy Rule.

B. BENEFITS OF THE PRIVACY RULE

The main benefit and stated goal of the Privacy Rule is the protection of personal health information. Not so much because that is the end in and of itself, but because the protection of that information will have far reaching effects on health care mainly as a result of quieting the concerns of patients about their concerns regarding their health information.

The Rule will improve the quality of care and the patient/provider relationship. As noted above, concerns about lack of privacy now drive a wedge between patients and their providers and impede the provision of quality of care because patients withhold information, avoid asking certain questions, or fail to seek care altogether. *Myths and Facts about the HIPAA Privacy Regulation, HIPAAdvisory, <http://www.hipaadvisory.com/views/Patient/myths.htm> (#30)*

Under the Rule, patient will have significant new rights to understand and control how their health information is used:

Patient education on privacy protections - Providers and health plans will be required to give patients a clear written explanation of how the covered entity may use and disclose their health information.

Ensuring patient access to their medical records - Patients will be able to see and get copies of their records, and request amendments. Also, a history of non-routine disclosures must be made accessible to patients.

Receiving patient consent before information is released - Health care providers who see patients will be required to obtain patient consent before sharing their information for treatment, payment and health care operations. In addition, separate patient authorization must be obtained for non-routine disclosures and most non-health care purposes. Patients will have the right to request restrictions on the uses and disclosures of their information.

Providing recourse if privacy protections are violated - People will have the right to file a formal complaint with a covered provider or health plan,

or with HHS, about violations of the provisions of this rule or the policies and procedures of the covered entity.

Protecting the Privacy of Patients' Health Information, HHS Fact Sheet, <http://www.hhs.gov/news/press/2001pres/01fsprivacy.html> (#5)

Regarding consent, this is the first time that federal law has established the principle that medical information may not be disclosed without the consent of the patient. *Ronald Weich, Legislative Consultant to the American Civil Liberties Union, National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality, August 22, 2001 (#14)*

C. COSTS OF THE PRIVACY RULE

Some note that the costs of implementing the privacy standards will dwarf the costs of both the security and administrative transactions standards (also part of HIPAA). *Comment # 1788i, Comments on NPRM: Standards for Privacy of Individually Identifiable Health Information, Use and Disclosure for Treatment, Payment, and Health Care Operations.* (#32) The costs will obviously be able to be measured monetarily, but they will also be able to be measured by the administrative burden.

Full compliance carries a significant and time-consuming administrative burden. An entity covered under the Rule is required to develop and implement a compliance plan that includes policies and procedures regarding: the use and disclosure of protected health information (PHI); the revocation of consents and authorizations, disclosures to Business Associates; disclosures to personal representatives of individuals; disclosures by workforce members, including whistleblowers; compliance with rules regarding the release of the minimum amount of information; creation of de-identified information; accountings; access to health information; and retention of information. *Frequently Asked Questions about HIPAA (#3)*

Originally, HHS predicted that the proposed rule would cost providers and insurers \$1.8 to \$3.6 billion. They now predict costs over a 10-year period will be about \$17.6 billion. Others put the cost at \$40 billion over the first 5 years. *Implications of the New Privacy Standards for Healthcare Institutions, Healthcare Financial Management, June 1, 2001. (#22)*

The rule is likely to have the most significant impact on smaller institutions and not-for-profit hospitals (#22) "One time" costs for hardware and security implementation are not insignificant costs when they may approach 10% or more of a hospital's operating budget. (#32)

The largest portion of the compliance expense will be the costs associated with the requirement of having a privacy officer and the implementation

of the minimum necessary standard. For privacy officer it is expected to cost \$723 million in the first year with a 10 year cost of \$5.9 billion. The minimum necessary standard is expected to cost \$926 million in the first year with a 10 year cost of 5.8 billion. (#22)

III. THE CONSENT REQUIREMENT:

Consent is perhaps the biggest change from the proposed rule because the proposed rule did not require consent for treatment, payment or health care operations. *John Christiansen, Preliminary Analysis of HIPAA Privacy Regulations: Information Privacy and Processes, January 2, 2001* (#40)

The Privacy Rule establishes a federal requirement that most doctors, hospitals, or other health care providers obtain a patient's written consent before using or disclosing the patient's personal health information to carry out treatment, payment, or health care operations (TPO). (#6) General provisions for consent are also listed in #6 and will be discussed in the paper.

Health care providers must obtain consent from the individual to use or disclose PHI for purposes of TPO. For the most part, other covered entities are not required to obtain consent to use or disclose PHI to carry out TPO (#24)

The consent form, itself, may be written in general terms, but must inform the patient that protected health information may be used for treatment, payment, or health care operations. It must also advise that the patient has the right to review the privacy notice prior to signing the consent. The consent must also state that the entity has reserved the right to change its privacy practice...(#24)

The consent must be maintained for 6 years (#6).

Health care providers may condition treatment on the individual providing consent (#6).

A Pharmacist may use professional judgment and experience with common practice to make reasonable inferences of patient's best interests in allowing a person other than the patient to pick up a prescription. 45 CFR 164.510(b).

The following are exempt from the consent requirement: emergency treatment situations, but covered entity must attempt to obtain consent as soon as reasonably practicable after the emergency care., when provider is required by law to provide the PHI, for law enforcement or other government purposes. Also indirect treatment providers do not need consent to use PHI because they deliver services based on the orders of other providers and the results of those services are furnished to the patient through the direct treating provider. (#6)

Authorizations are differentiated from consent - Authorizations are a more customized document that gives covered entities permission to use specified PHI for specified purposes, which are generally other than TPO, or to disclose PHI to a third party

specified by the individual. Covered entities may not condition treatment on the individual providing an authorization (#6)

Additionally, all covered entities, not just providers, must obtain authorizations.

A. CONCERNS REGARDING THE CONSENT REQUIREMENT

Because providers can condition treatment on the individual's providing consent, individuals may be coerced into sharing personal health information. *Sue A. Blevins, President, Institute of Health Freedom, Testimony before the National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality, August 21, 2001 (#9)*

Does this create a new ethics code - patients may now be denied treatment for failing to share personally identifiable information for purposes of health care operations? (#9).

Consent requirement will create unintended but significant barriers to delivery of health care services to Kaiser Permanente's 8.2 million members. *Mary Henderson, National HIPAA Program Director, Kaiser Permanente Testimony for above committee (#7)*

The Health Leadership Council states that the right of a provider to condition treatment upon the patient giving written consent is often meaningless within the ethical practice of medicine - as an example: a patient signs consent, later revokes the consent while hospitalized. Ethically and legally the provider must continue treatment, but under the Privacy Rule, would be required to do so without the benefit of medical information derived prior to the revocation. This puts the provider in an untenable ethical and legal position and puts the patient at risk. *Bruce Kelly, Director of Government Relations for Mayo Foundation, testifying on behalf of the Healthcare Leadership Council at the above committee (#10)*

Also see the consent requirement as an affront to patients - They do not think the first thing patients should have to face is a 10 page summary of information practices and a demand for a signed consent before they can be seen (#10).

Even within HIPAA there are incongruities. If a person withdraws consent, under the Privacy Rule, a provider can disenroll the patient. However HIPAA portability regulations generally preclude disenrollment of any member except for nonpayment or fraud - which controls? (#7).

If providers are prohibited from disclosing to health plans the protected health information necessary for collection analysis activities, the goal of accountability and oversight of health plans will be seriously jeopardized. *Sharon King Donohue, General Counsel of the National Committee for Quality Assurance (NCQA), testifying at above committee (#8).*

It is only through the collection analysis and action upon information that our health care system can hope to reduce the medical errors such as those described in the Institute of Medicine's report. (#8).

Without a patient's consent, a pharmacist can do nothing more with a patient's prescription than set it aside and wait for the patient to arrive and provide written consent.

In some situations such as identification of a contaminated, counterfeit or ineffective product, urgent notification of the patient is required. *Susan C. Winckler, RPh, JD, before the above committee (#13).*

B. RECOMMENDATIONS FOR CONSENT REQUIREMENT

Several entities recommend doing away with the consent requirement for TPO (the proposed rule did not have the consent requirement) (#12, #8, #13)

Uses and disclosures of protected health information created or received prior to the compliance date of the Rule should be allowed to continue as was legally permitted prior to the effective date of the rule without regard to content or existence of written consent (#12).

The AMA believes conditional treatment on patient's consent only for routine and necessary purposes, such as TPO. (#12).

IV. THE MINIMUM NECESSARY STANDARD

The minimum necessary standard generally requires covered entities to take reasonable steps to limit use or disclosure of PHI to minimum necessary to accomplish the intended purpose. CFR § 164.502(b).

The standard does not apply to:

- Disclosures to or request by a health care provider for treatment purposes.
- Disclosures to individuals who are the subject of the information.
- Uses or disclosures made pursuant to an authorization by the individual.
- Uses or disclosures required for compliance with standardized HIPAA transactions.
- Disclosures to HHS.
- Uses or disclosures required by law. CFR § 164.502(b).

For uses of PHI, the policies and procedures must identify the persons or classes of persons within the covered entity who need access to the information to carry out their job duties, the types of PHI needed, and conditions appropriate to such access.

For routine disclosures, covered entities must develop reasonable criteria for determining, and limiting disclosure to only the minimum amount of PHI necessary to

accomplish the purpose of a non-routine disclosure. Non-routine disclosures must be made on an individual basis. (#6)

In some circumstances, the Rule permits a covered entity to rely on the judgment of the party requesting the disclosure as to the minimum amount of information necessary. It is permitted when the request is made by:

- A public official or agency for a disclosure permitted under §164.512
- Another covered entity
- A professional who is a workforce member or business associate of the covered entity holding the information.
- A researcher with appropriate documentation from an IRB or Privacy Board.

(#6)

The ACLU believes that the minimum necessary standard embodies the essence of the privacy rule. It gives meaning to the presumption that information is not to be disclosed to third parties unless that disclosure is necessary to carry out a specific purpose, and then only to the extent necessary to carry out a specific purpose. (#14)

A. CONCERNS REGARDING THE MINIMUM NECESSARY STD.

Because the minimum necessary standard is inherently vague, HIAA is concerned that it will lead to "defensive" restrictions on the flow of information between providers and health plans due to fears about the legal risk of disclosing information.. They further believe this may have a negative consequence for the quality and affordability of health coverage. *Henry R. Desmarais, MD, MPA, Senior Vice President for Policy and Information, Health Insurance Association of America, at the above committee (#11).*

This sentiment is shared by the American Pharmaceutical Association (APhA), who stated that providers might be reluctant to share information in an attempt not to violate the minimum necessary standard. (#13)

The NCQA believes the minimum necessary standard is a costly and administrative burden and will interfere with important health care operations (#7).

In making the minimum necessary determinations, covered entities concerned over the ambiguity of the rule, coupled with a reasonable fear of enforcement action, may limit certain information below the level critical for quality assurance, disease management or accreditation. These incentives for disclosing insufficient clinical data could inadvertently thwart quality enhancing activities that are beneficial to consumers (#7).

Patients should understand that "minimum necessary" bears little relationship to the potential harm from disclosure. Information is much more likely to be segregated by type than by sensitivity. Because of this a categorical request

for information, such as lab tests, may reveal sensitive information that the requestor did not need to know. *Kathryn Serkes, Public Affairs Counsel, Association of American Physicians and Surgeons, at the above committee, (#18).*

The minimum necessary information might be just as prejudicial, perhaps moreso if out of context, than the total chart, and is thus of no help in allaying patients' concerns (#18).

AAPS believes that the minimum necessary standard is undefined, and therefore unenforceable. The standard recalls the "Mad Hatter's pronouncement of it means what he says it means". Further, the OCR has no authority to override the requestor. (#18).

According to AAPS, the worst feature of the minimum necessary standard is that law enforcement is exempt... (#18).

B. RECOMMENDATIONS FOR THE MINIMUM NECESSARY STD.

AHA recommends eliminating restrictions on the use of patient information within the hospital and easing restrictions for other uses and disclosures. This would take care of a scenario such as: A nurse walking by a patient in distress may not have ready access to all the information the nurse needs to help because she isn't authorized to see those records. *AHA: Medical Privacy Rules Need to be Fixed for Patients and Caregivers,*
<http://www.aha.org/info/releasedisplay.asp?passreleaseid=332>

HIAA recommends that the minimum necessary standard be removed from the Privacy Rule. In their view the other substantial protections established by the rule are sufficient to create strong safeguards for the confidentiality of protected health information while avoiding the potentially serious complications the minimum necessary standard presents. (#11)

Rather than having the minimum necessary standard, AAPS recommends the requestor should request either a copy of the record within certain parameters (date, type of info, etc) or for a specified set of information to be abstracted from the record (#18). This would not require an "omniscient person fully cognizant of the content of the record, the needs of the requestor, and the mindset of the enforcer." (#18).

V. STATE PREEMPTION

All state laws that are contrary to the rule are preempted unless one of four conditions are met

I will explain the four conditions.

A. CONCERNS WITH STATE PREEMPTION

B. RECOMMENDATIONS FOR STATE PREEMPTION

VI. RECOMMENDATIONS

I am not sure of my final recommendations at this point.

VII. CONCLUSION

Chuck Tripp

THESIS TOPIC:

THE HIPAA PRIVACY RULE'S IMPACT

ON THE COST, ACCESS AND QUALITY OF HEALTH CARE

Congress recognized the need for national patient record privacy standards in 1996 when they enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA). While the law included provisions designed to save money for health care businesses by encouraging electronic transactions, it also required new safeguards to protect the security and confidentiality of that information. The law gave Congress until August 21, 1999 to pass comprehensive health privacy legislation. When that did not happen, the law required the Department of Health and Human Services (HHS) to craft such protections by regulation - The Privacy Rule. The initial proposed regulations were published in November 1999 and attracted over 52,000 comments. The final rule was published in December 2000 with an effective date of April 14, 2001. As required by law most covered entities have two years - until April 14, 2003 to comply with the final rule's provisions.

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The minimum necessary standard requires a covered entity to make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. This requirement does not apply to disclosures to or requests by a health care provider for treatment, disclosures to the individual who is the subject of the information, disclosures made to the Secretary of Health and Human Services, and uses or disclosures that are required by law. For routine and recurring disclosures of protected health information, the covered entity must implement policies and procedures that limit the protected health information to the amount reasonably necessary to achieve the purpose of the disclosure. For non-recurring disclosures, the covered entity must develop criteria to limit the protected health information being disclosed, and review requests for disclosure on an individual basis in accordance with such criteria. The regulation further provides that a covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when the request is made by a public

official, another covered entity, a professional who is a workforce member or business associate of the covered entity holding the information, or a researcher with appropriate documentation from an Institutional Review Board (IRB) or Privacy Board.

The minimum necessary standard has also stimulated concern. A spokesperson for the Health Insurance Association of America (HIAA) testifying before the National Committee on Vital and health Statistics Subcommittee on Privacy and Confidentiality, stated, "Because the minimum necessary standard is inherently vague, we are concerned that it will lead to "defensive" restrictions on the flow of information between providers and health plans due to fears about the legal risk of disclosing information. We believe this may have negative consequences for the quality and affordability of health care." He stated, additionally, that the minimum necessary standard will be very costly to implement, up to \$19.8 billion over five years for hospitals alone. A spokesperson for the American Association of Health Plans (AAHP), also testifying before the subcommittee, stated, "If the privacy rule is at all vague or ambiguous about what a health plan may do, the plaintiff's bar will use it as a weapon." He recommended that HHS clarify the guidance to say that the standard is satisfied so long as the covered entity reasonably believes that the information is necessary to perform the task at hand.

The privacy rule, while it is a final rule, is subject to modification. Based on my research to date, I expect that modifications are imminent. A noted aim of HHS is that the privacy protections not interfere with a patient's access to or the quality of health care delivery. My paper, while focusing on the above two provisions of the Privacy Rule, will analyze the concerns of interested parties, measure them against the actual provisions in the regulation, and will propose a means of implementing the rule that will best protect

the individually identifiable health information while minimizing its impact on the cost, access and quality of health care.

**THE HIPAA PRIVACY RULE:
ANOTHER STOP ALONG THE ROAD
PAVED WITH GOOD INTENTIONS**

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April 15, 2002

This paper is submitted to Professor Sullivan in satisfaction of the Seton Hall Law School's LLM Thesis Requirement.

This paper was fully researched and in final draft form before HHS published its proposed modifications on March 27, 2002. The paper's recommendations were also finalized before this date. The paper was modified, however, to incorporate HHS's proposed modifications and compare them to the paper's recommendations.

The views expressed in this article are those of the author and do not reflect the official policy or position of the United States Air Force, Department of Defense, or the U.S. Government.

Thesis
Chuck Tripp
15 Apr 2002

**THE HIPAA PRIVACY RULE:
ANOTHER STOP ALONG THE ROAD
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I. INTRODUCTION:

As is true with essentially all legislation and resultant regulations, the initiating party's intentions are good. Also, true, however, is the fact that somewhere in the process perhaps in the translation from statute to regulation, something seems to get lost in the translation, and those good intentions somehow get overtaken by the harsh realities of the actual implementation of the statute or regulation. Such is the case with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule.

The Act gave Congress until August 21, 1999 to pass comprehensive health privacy legislation. In the event that did not happen, the Act required the Department of Health and Human Services (HHS) to craft such protections by regulation -- The Privacy Rule.¹ The initial proposed regulations were published in November 2000 and attracted over 52,000 comments.² The Final Rule was published in December 2000 with an effective date of April 14, 2001. As required by law, most covered entities have two years, until April 14, 2003, to comply with the Final Rule's provisions.³

¹ U.S. Department of Health and Human Services. "Protecting the Privacy of Patients' Health Information." HHS Fact Sheet, 6 July 2001. 4 Sep 2001 <http://www.hhs.gov/news/press/2001pres/01fsprivacy.html>.

² Id.

³ Office for Civil Rights, OCR HIPAA Privacy TA 164.000.001 General Overview, 3. 24 Sep. 2001 <http://www.hhs.gov/ocr/hipaa/genoverview.html>. Small health plans will have three years, until April 14, 2004, to comply with the Final Rule's provisions.

The Privacy Rule engendered a great deal of response from the health care community, as evidenced by the 52,000 comments. Every part of that community, from health care providers, insurers, and pharmacists, to health-related advocacy groups voiced both support and concern over the then-proposed Privacy Rule. This paper will examine the Final Rule, focusing on two key aspects, the Consent requirement and the Minimum Necessary standard, will discuss its likely impact on the costs and quality of health care, and will propose changes to the Privacy Rule, specifically pertaining to the Consent requirement and the Minimum Necessary standard, that will maximize its potential to serve its stated three purposes (See Section II), while minimizing its adverse impact on the cost and quality of health care. Section II will discuss the purpose of the Privacy Rule. Section III will provide a brief overview of the Privacy Rule. Section IV will examine the Consent requirement. Section V will examine the Minimum Necessary standard. Section VI will discuss concerns about the Final Rule, particularly the Consent requirement and the Minimum Necessary standard, voiced by various groups in the health care community, and will discuss the recommendations of the various health care groups. Section VII will discuss the Privacy Rule's effect on the cost and quality of health care. Section VIII will discuss the HHS' proposed modifications. Section IX will propose changes to the Privacy Rule, based on the concerns and recommendations of the organizations within the health care community, the costs and benefits of the Final Rule.

This paper concludes that the Consent requirement is not necessary to ensure medical privacy, and, in fact, will cause significant problems in the every day provision of health care; and, thus, recommends it be deleted from the Privacy Rule. The paper also concludes that the Minimum Necessary standard, while beneficial, is misguided in

its implementation; and, therefore, recommends that it be modified to reduce costs associated with the standard, as well as to increase its effectiveness in ensuring quality health care.

II. THE PURPOSE OF THE PRIVACY RULE

The Privacy Rule establishes, for the first time, a set of national privacy standards that will provide all Americans with a basic level of protection and peace of mind, which is essential to their participating fully in their medical care.⁴ The Privacy Rule has three major purposes:

1. to protect and enhance the rights of consumers by providing them access to their health information and controlling the inappropriate use of that information;
2. to improve the quality of health care in the U.S. by restoring trust in the health care system among consumers, health care professionals, and the multitude of organizations and individuals committed to the delivery of care; and
3. to improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on efforts by states, health systems, and individual organizations and individuals.⁵

The provision of high-quality health care requires the free exchange of personal, often-sensitive, information between a patient and a health care provider. The patient's ability to trust that the provided information will be protected and kept confidential is vital. Many patients, however, are concerned that their health information is not protected. Factors which fuel this concern are the growth in the number of organizations involved in providing health care and processing medical claims, the growing use of electronic information technology, increased efforts to market health care and related

⁴ Final Privacy Rule Preamble, Background and Purpose, 9. 27 Nov 2001
<http://aspe.hhs.gov/admnsimp/final/PvcPre01.htm>.

⁵ Id. at 8.

products to consumers, and the increasing technological ability to collect highly sensitive information, such as genetic information, about a person's current and future health status.⁶

Surveys are replete with statistics indicating consumer's concern over health care privacy issues.⁷ The Committee on Maintaining Privacy and Security in Health Care Applications of the National Information Infrastructure made several findings highlighting the need for heightened privacy and security: "The greatest concerns regarding privacy of health information derive from widespread sharing of patient information throughout the health care industry and the inadequate federal and state regulatory framework for systematic protection of health information."⁸ These concerns regarding the privacy of health information, unfortunately, are not merely theoretical. Examples of recent privacy breaches include:

A Michigan-based health system accidentally posted the medical records of thousands of patients on the Internet (The Ann Arbor News, February 10, 1999).

A Utah-based pharmaceutical benefits management firm used patient data to solicit business for its owner, a drug store (Kiplingers, February 2000).

An employee of the Tampa, Florida, health department took a computer disk containing the names of 4,000 people who had tested positive for HIV, the virus that causes AIDS (USA Today, October 10, 1996).

A Nevada woman who purchased a used computer discovered that the computer still contained the prescription records of the customers of the pharmacy that had previously owned the

⁶ Id. at 9

⁷ A 1998 study found that 88 percent of consumers were "concerned" by the amount of information being requested, while 55 percent were "very concerned". A series of national public opinion polls conducted by Louis Harris & Associates documents a rising level of public concern about privacy, growing from 64 percent in 1978 to 82 percent in 1995. Over 80 percent of persons surveyed in 1999 agreed with the statement that they had "lost all control over their personal information. Id. at 11.

⁸ Id. at 27.

computer. The pharmacy data base included names, addresses, social security numbers, and a list of all the medicines the customers had purchased (The New York Times, April 4, 1997 and April 12, 1997).⁹

A breach of a person's health privacy can have far-reaching implications beyond the physical health of the person, including the loss of a job, loss of health insurance, and public humiliation. Examples of such breaches follow:

A banker who also sat on a county health board gained access to patients' records and identified several people with cancer and called in their mortgages. See the National Law Journal, May 30, 1994.

A candidate for Congress nearly saw her campaign derailed when newspapers published the fact that she had sought psychiatric treatment after a suicide attempt. See New York Times, October 10, 1992, Section 1, page 25.

A 30-year FBI veteran was put on administrative leave when, without his permission, his pharmacy released information about his treatment for depression. (Los Angeles Times, September 1, 1998).¹⁰

Concerns about the lack of privacy of individuals' personal health information, is, unfortunately, but understandably, resulting in people shying away from medical treatment. Recent studies indicate that a person who does not believe his medical privacy will be protected is much less likely to fully participate in the diagnosis and treatment of his own medical condition.¹¹ One in six Americans reported that they have taken some sort of evasive action to avoid the misuse of their health information by providing inaccurate diagnostic information to a health care provider, changing physicians, or avoiding care altogether.¹²

⁹ Id. at 15.

¹⁰ Id. at 17.

¹¹ Id. at 16.

¹² Id. at 17.

The findings are troubling because the essence of the health care system is built on trust between the patient and the health care provider. Trust allows patients to share the most intimate details of their lives with their health care providers. In the absence of such trust and the resultant withholding of candid information, there is serious risk that the treatment plan will be inappropriate to the patient's situation.¹³ The accuracy of the health information, however, effects more than the patient's treatment. Accurate medical records ensure prompt and proper processing of claims for payment, assist communities in identifying troubling public health trends, and perhaps most importantly, facilitate continued improvements in the quality of health care by providing valuable information about which treatments work, and which do not.¹⁴

Because of these concerns and the importance of encouraging the free-flow of accurate health information from the patient to the health care provider, it is imperative to protect health information privacy. Prior to 1996, rules protecting health information privacy had been enacted primarily by the states. While virtually all states have statutes to protect health information privacy, the laws vary greatly from state to state, and tend not to cover the entire health care system.¹⁵ As such, state laws do not adequately silence the concerns of health information privacy. The answer to these concerns cannot be found in a patchwork of state laws, nor is the answer for consumers to withdraw from society and the health care system. The answer, rather, is to establish a clear national legal framework for health information privacy -- the Privacy Rule.¹⁶

III. THE PRIVACY RULE GENERALLY

¹³ Id. at 16.

¹⁴ Id.

¹⁵ Id. at 9.

¹⁶ Id. at 18.

The Privacy Rule applies only to "covered entities" -- health plans, health care clearinghouses¹⁷, and health care providers who transmit certain health information electronically.¹⁸ The focal point of the Privacy Rule is the general prohibition on the dissemination of what the Rule defines as "protected health information" (PHI)¹⁹. The Rule states that, "A covered entity may not use or disclose protected health information except as permitted or required" by the rule.²⁰ The Rule provides for *permitted* uses²¹ and disclosures²² and *required* disclosures. Most notably, a covered entity is *permitted* to use or disclose protected health information pursuant to a Consent to carry out treatment, payment, or health care operations²³ (TPO), or pursuant to an Authorization for uses

¹⁷ "A public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions

- Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.
- Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity." Final Privacy Rule--Regulation Text, 45 CFR § 160.103, 4. 24 Sep. 2001 <http://www.hhs.gov/ocr/regtext.html>.

¹⁸ Id. at 45 CFR § 160.102, 2.

¹⁹ "Information that is a subset of health information, including demographic information collected from an individual, and:

- Is created or received by a health care provider, health plan, employer, or health care clearinghouse;
- Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
- That identifies the individual; or
- With respect to which there is a reasonable basis to believe the information can be used to identify the individual. Id. at 45 CFR § 164.501, 18.

²⁰ Id at 45 CFR § 164.502, 22.

²¹ "With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information." Id.

²² "The release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information." Id. at 45 CFR § 164.501, 16.

²³ "Any of the following activities of the covered entity to the extent that the activities are related to covered functions, and any of the following activities of an organized health care arrangement in which the covered entity participates:

- Conducting quality assessment and improvement activities.
- Reviewing the competence or qualifications of health care professionals...

other than TPO.²⁴ A covered entity is *required* to disclose PHI to the individual who is the subject of the PHI, and when required by the Secretary for compliance and enforcement purposes.²⁵

Under the Final Rule, patients will have significant, new rights to understand and control how their health information is used:

- *Patient education on privacy protections.* Providers and health plans will be required to give patients a clear written explanation (Notice) of how the covered entity may use and disclose their health information.
- *Ensuring patient access to their medical records.* Patients will be able to see and obtain copies of their records, and request amendments. In addition, a history of non-routine disclosures must be made accessible to patients.
- *Receiving patient consent before information is released.* Health care providers who see patients will be required to obtain patient consent before sharing their information for treatment, payment, and health care operations. In addition, separate patient authorization must be obtained for non-routine disclosures and most non-health care purposes. Patients will have the right to request restrictions on the uses and disclosures of their information.
- *Providing recourse if privacy protections are violated.* Patients will have the right to file a formal complaint with a covered provider or health plan, or with HHS, about violations of the provisions of this rule or the policies and procedures of the covered entity.²⁶

Two key provisions of the Rule are the Consent requirement, §164.506, and the Minimum Necessary standard, §§ 164.502(b) and 164.514(d). These two provisions are

-
- Underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits.
 - Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs.
 - Business planning and development.
 - Business management and general administrative activities of the entity." Id.

²⁴ Final Privacy Rule, supra note 17, at 45 CFR § 1164.502, 22.

²⁵ Id.

²⁶ U.S. Department of Health and Human Services, supra note 1, at 2.

the essence of the Rule, and, as evidenced by the concerns voiced within the health care field, which will be discussed in Section VII, they are, perhaps, the most controversial. Most importantly, they both can greatly impact both the costs and quality of health care.

IV. CONSENT REQUIREMENT AND AUTHORIZATIONS

A. Consent Requirement

The Privacy Rule establishes a federal requirement that most health care providers obtain a patient's written consent before using or disclosing the patient's personal health information (PHI) to carry out treatment, payment, or health care operations (TPO).²⁷ The goal of the Consent requirement is to encourage more informed discussions between patients and health care providers about how protected health information will be used and disclosed in the health care system.²⁸ Many health care providers already obtain patient consent, stating they are ethically obligated to do so and that it is their practice to do so. A 1998 study by Merz, et al, referenced in the preamble to the Final Rule, examined consent forms regarding disclosure of medical information. The study found that "97% of all hospitals seek consent for the release of information for payment purposes; 45 % seek consent for disclosure for utilization review, peer review, quality assurance, and/or prospective review; and 50% seek consent for disclosure to providers, other health care facilities, or others for continuity of care purposes."²⁹ The Privacy Rule builds on these practices by establishing a uniform federal standard for most health care

²⁷ Office for Civil Rights, Standards for Privacy of Individually Identifiable Health Information, 5, 4 Sep. 2001 <http://aspe.os.dhhs.gov/admnsimp.final/pvcguide1.htm>.

²⁸ Final Privacy Rule Preamble, Part I, 28.

²⁹ Jon F. Marz, Pamela Sanka, Simon S. Yoo, "Hospital Consent for Disclosures of Medical Records", 26 J.L.M & Ethics, no. 3, (1998), 241-48.

providers to obtain their patients' consent for uses and disclosures of health information to carry out TPO.³⁰

The Consent requirement is found at § 164.506 of the Privacy Rule. It provides that, absent a specified exception, a covered *health care provider* must obtain the patient's consent prior to using or disclosing protected health information for TPO.³¹ The Rule singles out health care providers in requiring them to obtain consent; neither health plans, nor health care clearinghouses are required to obtain consent, although neither is prohibited from doing so. One of the main exceptions to requiring consent is providers who have an indirect treatment relationship.³² As the name implies, they have no direct relationship or contact with the patient. Rather, they have a relationship with the patient's direct provider and are providing care to the patient for the direct care provider; they report any results back to the direct care provider, rather than to the patient. Thus, only health care providers who have a direct treatment relationship with the patient must obtain consent.

A consent under §164.506 must be written in plain language, understandable to the average patient, and must inform the individual that protected information (PHI) may be used and disclosed to carry out TPO. The consent must refer the individual to the notice required by §164.520, and inform him or her of the right to review the notice before signing the consent. It must also inform the individual that the notice is subject to change. The consent must state that the individual has the right to request that the covered entity restrict the use or disclosure of his or her PHI and that the covered entity is not required to agree to a requested restriction; but, if it does, the restriction is binding on

³⁰ Office for Civil Rights, *supra* note 27, at 5.

³¹ Final Privacy Rule, *supra* note 18, at 34.

³² *Id.*

the covered entity. The consent must also inform the individual of his or her right to revoke the consent in writing, except to the extent that the covered entity has taken action in reliance of the consent. Finally, the consent must be signed and dated by the individual.³³

The consent requirement for direct treatment health care providers logically dictates that, without such consent, the provider is prohibited from either using or disclosing a patient's personal health information for TPO. It, therefore follows, and the Rule provides, that health care providers can condition treatment on the provision of consent from the individual.³⁴ Therefore, if an individual refuses to provide consent, the provider may refuse to treat that person. The Rule also allows health plans, but does not obligate them, to condition enrollment in the health plan on the provision of consent from the individual.³⁵ Additionally, the Rule allows individuals to revoke their consent in writing at any time, except to the extent that the covered entity has taken action in reliance on that consent. Further, if an individual revokes his or her consent, the covered entity may refuse to continue treatment of that individual.³⁶

As noted above, there are exceptions to the consent requirement in addition to the indirect treatment exception. A covered health care provider may use or disclose PHI for TPO, without prior consent, in three situations: in emergency treatment situations; in situations where the provider is required by law to treat the individual; and in situations where the provider is unable to obtain consent due to communication barriers. Each of these exceptions, however, requires that the provider attempt to obtain consent form the

³³ Id. at 36.

³⁴ Id. at 35.

³⁵ Id.

³⁶ Final Privacy Rule Preamble, Part II, 70.

individual, and that he or she document the attempts and reasons why such attempts were unsuccessful.³⁷

The original, proposed Privacy Rule did not contain a Consent requirement; rather, it allowed for uses and disclosures of PHI for TPO without consent because of HHS's concern that any consent would not be voluntary, but rather "coercive"--either provide consent or do not receive treatment.³⁸ There was also concern that blanket consents provided individuals neither notice nor control over how their health information would be used. The Consent requirement is still "coercive" in that treatment may be contingent upon the individual providing his or her consent, but HHS recognized, through many comments on the subject, that the act of providing and obtaining consent represent important values for both patients and health care providers.³⁹ In fact, patient advocates argued that the act of signing the consent form focuses the patient's attention on the substance of the transaction and provides the patient an opportunity to ask questions and negotiate the use and disclosure of his or her health care information.⁴⁰

The issue of "coerced" consent is not only mentioned by HHS in the Preamble, but also by several representatives in the health care community and is discussed further in Section VI. While it is true that the Consent provided in the Privacy Rule is not truly voluntary in the sense that failure to provide consent will most likely result in the individual not receiving medical treatment, it cannot truly be characterized as being "coercive". Black's Law Dictionary (Black's) defines "coerce" as, "Compelled to

³⁷ Id.

³⁸ Final Privacy Rule Preamble, Part I, 27.

³⁹ Final Privacy Rule Preamble, Part III

⁴⁰ Id.

compliance; constrained to obedience, or submission in a vigorous or forcible manner."⁴¹

It is certainly not criminal coercion, which Black's defines as, "A person is guilty of criminal coercion if, with purpose to unlawfully restrict another's freedom of action to his detriment, he threatens to: (a) commit any criminal offense; or (b) accuse anyone of a criminal offense; or (c) expose any secret tending to subject any person to hatred, contempt or ridicule, or to impair his credit or business repute; or (d) take or withhold action as an official, or cause an official to take or withhold action."⁴² Duress is often associated with coercion. Black's defines it as, "A condition where one is induced by wrongful act or threat of another to make contract under circumstances that deprive him of exercise of his free will."⁴³ While the health care community's use of "coerce" does not meet the "legal" definitions of the word or associated words, it is widely used in the community and is a source of great concern in the community; therefore, references to it are in this paper, and should be understood as "non-voluntary", rather than "coercive".

While the Consent requirement provides notice and protection for the use and disclosure of PHI for TPO, the Rule authorizes disclosures of PHI for activities other than TPO.

B. Authorizations

§ 164.508 of the Rule provides for Authorizations. In order to use and disclose protected health information for purposes other than TPO, a covered entity must obtain an Authorization.⁴⁴ While only health care providers are required to obtain Consent for TPO, all covered entities are required to obtain an Authorization from an individual in

⁴¹ Black's Law Dictionary 234 (5th ed. 1979).

⁴² Id. at 235.

⁴³ Id. at 452.

⁴⁴ Andrew B. Wachler and Phyllis A. Avery, "Complex Privacy Regulations Have Far Reaching Impact", 13 No. 3 Health Law, 7 (April 2001).

order to use or disclose protected health information for ancillary purposes, such as marketing, pre-enrollment underwriting, or employment determinations.⁴⁵ An authorization must be written in more specific terms than a Consent, and a covered entity is not allowed to condition treatment on the provision of an Authorization.⁴⁶

The prohibition on conditioning treatment on an authorization is intended to prevent covered entities from "coercing" individuals into authorizing a use or disclosure of their PHI that is not necessary to carry out the primary services that the covered entity provides. As an example, "A health care provider could not refuse to treat an individual because the individual refused to authorize a disclosure to a pharmaceutical manufacturer for the purpose of marketing a new product."⁴⁷ There is, however, an exception to this prohibition. When a covered entity provides treatment for the sole purpose of providing information to a third party, the covered entity may condition that treatment on the obtaining of an authorization to use or disclose PHI necessary for that purpose. An example of this is, "A covered health care provider may have a contract with an employer to provide fitness-for-duty examinations to the employer's employees. The provider may refuse to conduct the examination if an individual refuses to authorize the provider to disclose the results of the examination to the employer."⁴⁸

In order for an authorization to be valid, it must contain the following elements:

- A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;

⁴⁵ HIPAAAdvisory, "Consents and Authorizations Explored", 4 Jan. 2002
<http://www.hipaadvisor.com/action/advisor/HIPAAAdvisor12.htm>.

⁴⁶ Andrew B. Wachler, *supra* note 44.

⁴⁷ Final Privacy Rule Preamble, Part II, 78.

⁴⁸ *Id.* at 79.

- The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
- The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure;
- An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure;
- A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization;
- A statement that information used or disclosed pursuant to the authorization may be subject to redisclosure by the recipient and no longer be protected by this rule;
- Signature of the individual and date; and
- If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual.⁴⁹

V. MINIMUM NECESSARY STANDARD

The Minimum Necessary standard arose from the concern that an individual's medical records and other protected health care information were accessible to too many people. It is not a strict standard, or a specifically defined one; rather, it is intended to make covered entities evaluate their current practices and implement procedures and protections, as needed, to prevent unnecessary disclosures of protected health information.⁵⁰

⁴⁹ Final Privacy Rule, supra note 18, at 40

⁵⁰ HIPAAdvisory, "When Does "Minimum Necessary" Apply?", 1, 4 Jan. 2002
<http://www.hipaadvisory.com/action/advisor/HIPAAuthor18.htm>.

The Privacy Rule organizes the varying uses and disclosures of protected health information into three categories and imposes different requirements for compliance with the Minimum Necessary standard for each category:

- Internal Use of PHI. Covered entities are required to audit their operations and identify the persons or classes of persons within their operations who need access to PHI to carry out their job duties, the categories or types of PHI that each of these classes of people require, and under what conditions such persons will need to access the PHI necessary to perform their jobs. Policies and procedures must be implemented to ensure that the use of PHI remains limited to the necessary scope as identified in the audit.
- Routine Disclosures. For routine or recurring requests and disclosures, covered entities must develop standard protocols, policies, and procedures which limit the PHI disclosed or requested to the minimum necessary to achieve the purpose of that particular disclosure or request. Each disclosure does not have to be individually reviewed.
- Non-Routine Disclosures. Covered entities are required to develop criteria that will allow them to consistently determine the minimum amount of PHI necessary to accomplish the intended purpose of the disclosure in response to non-routine requests. Unlike the preceding categories, non-routine requests must be evaluated on an individual case-by-case basis in accordance with the criteria developed by the covered entity to ensure the minimum necessary disclosure.⁵¹

The Minimum Necessary Standard does not apply to the following uses and disclosures:

- Disclosures to or requests by a health care provider for treatment purposes.
- Disclosures to individuals who are the subject of the information.
- Uses or disclosures made pursuant to an authorization by the individual.

⁵¹ Id. at 2.

- Uses or disclosures required for compliance with standardized HIPAA transactions.
- Disclosures to HHS.
- Uses or disclosures required by law.⁵²

Oddly, while there are no exceptions to the Minimum Necessary standard in the Rule regarding uses of PHI, there is an exception for disclosures for treatment purposes. Therefore, a covered entity must apply the Minimum Necessary standard internally for treatment purposes, but does not have to do so with respect to outside providers for treatment purposes. Additionally, a covered entity may rely, if reasonable, on a requested disclosure for PHI as being the minimum necessary for the given purpose.⁵³ Based on this reliance, a covered entity making such a request must limit the request for protected health information to that minimum necessary to accomplish the purpose for which the request is made.⁵⁴ A covered entity may also rely on the assertions of professionals, such as attorneys and accountants, who are either its employees or employees of its business associates, regarding what protected health information is needed in order for them to provide the necessary professional services to the covered entity when such person represents that the requested information is the minimum necessary.⁵⁵

Also of note is the use or disclosure of medical records. For all uses, disclosures, and requests for which the Minimum Necessary standard applies, a covered entity may not use, disclose, or request (UDR) an entire medical record, except when the entire medical record is specifically justified as reasonably necessary to accomplish the purpose

⁵² Final Privacy Rule--Regulation Text, 23.

⁵³ Id. at 62.

⁵⁴ Id.

⁵⁵ Final Rule Preamble, Part II

of the UDR.⁵⁶ Further, UDR for the entire medical record absent such documented justification is a presumptive violation of the Rule.⁵⁷ This medical record rule does not apply in situations where a medical record is being disclosed to an outside health care provider for treatment purposes because the Minimum Necessary standard does not apply in that situation. The medical record rule does apply, however, to uses within a covered entity for treatment purposes. The Minimum Necessary standard appears to put more faith in external disclosures between entities that may or may not know each other than it does in internal uses by providers who most likely know and work with each other on a daily basis.

The Minimum Necessary standard is intended to reflect professional judgment and standards. HHS expects that covered entities will implement policies that allow persons involved in treatment to have access to the entire record, as reasonably needed.⁵⁸ The Minimum Necessary standard does not apply strict parameters around the definition of "Minimum Necessary"; rather, each covered entity should develop policies and procedures that will work for it. Because of this, HHS is likely to look at best practices across the health care industry when making determinations on compliance.

The Minimum Necessary standard is seen by many to be the embodiment of the Privacy Rule. It gives meaning to the presumption that health care information is not to be disclosed to third parties unless that disclosure is necessary to carry out a specific purpose, and then only to the extent necessary to carry out that specific purpose.⁵⁹ This

⁵⁶ Final Privacy Rule, *supra* note 18, at 63.

⁵⁷ Final Rule Preamble, Part II

⁵⁸ *Id.*

⁵⁹ Ronald Weich , "Significance of the 'Minimum Necessary' Standard." National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality. Washington D.C., 2, 22 Aug. 2001. 24 Sep. 2001 <http://www.ncvhs.hhs.gov/010822p4.htm>.

standard directly attacks the sloppy practice in today's medical record keeping, in which a valid request for one aspect of a patient's record leads to the disclosure of the entire record.

VI. HEALTH CARE COMMUNITY CONCERNS AND RECOMMENDATIONS

The health care community has a vested interest in the Privacy Rule and, not surprisingly, has made its interests known to the regulators. The Subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics held hearings in August 2001 on the Privacy Rule. Testimony at the hearing was received from a cross-section of the health care community, including: The National Committee for Quality Assurance (NCQA); Kaiser Permanente; the Institute for Health Freedom; the Mayo Foundation; the Health Insurance Association of America (HIAA); the American Medical Association (AMA); the American Pharmaceutical Association (APhA); the American Association of Health Plans (AAHP); the National Association of Community Drug Stores (NACDS); the National Association of Insurance Commissioners (NAIC); the Association of American Physicians and Surgeons (AAPS); the Association of American Medical Colleges (AAMC); and the Disease Management Association of America (DMAA). While each organization commended the overall thrust of the Privacy Rule, each voiced concerns about the Rule's impact from its own perspective, specifically focusing on the consent requirement and the minimum necessary standard. Based on the concerns, each organization made recommendations to best alleviate the adverse impacts of the Rule, while maintaining the Rule's overarching purpose.

A. Consent Requirement Concerns

While each organization has concerns from its own perspective, they can be grouped into four main categories: the coercive nature of the consent requirement; the administrative burden of the consent requirement; the broad definition of health care operations; and the effects of revocation of consent.

The "coercive" nature of the consent requirement. "Informed consent describes a condition appropriate only when data providers [patients] have a clear choice. They must not be, nor perceive themselves to be, subject to penalties for failure to provide the data sought."⁶⁰ The consent requirement in the Privacy Rule does not meet this definition. In fact, it specifically states, "A covered health care provider may condition treatment on the provision by the individual of a consent..." and further states, "A health plan may condition enrollment in the health plan on the provision by the individual of a consent under this section sought in conjunction with such enrollment."⁶¹ The consent requirement will, therefore, serve to "coerce" prospective patients into allowing their PHI to be used and disclosed for TPO.

While it makes sense that a health care provider would need access to a patient's medical record in order to treat him or her, the "coercive" nature of the consent requirement could put health care providers in an adversarial position to the patient. The main concern with the "coercive" nature of the consent requirement does not appear to involve the relationship to uses and disclosures for either treatment or payment purposes; the main concern, rather, is in relation to uses and disclosures for health care operations.

⁶⁰ George T. Duncan, Thomas B. Jabine, and Virginia A. de Wolfe, Private Lives and Public Policies: Confidentiality and Accessibility of Government Statistics, (Washington, DC: National Academy Press, 1993) quoted in Sue Blevins, Testimony. National Committee on Vital and Health Statistics Subcommittee on Privacy and Confidentiality, Washington D.C. 21 August 2001. 24 Sep 2001

<http://www.ncvhs.hhs.gov/010821p4.htm>.

⁶¹ Final Privacy Rule, supra note 18, at 35.

Ms. Sue Blevins, President of the Institute for Health Freedom, stated in her testimony before the Subcommittee, "The rule codifies a new ethical code for medical care in the United States: individuals now may be denied medical treatment for failing to share personally identifiable information for purposes of 'health care operations...'"⁶² The Hurley⁶³decision -- the "No Duty Rule", is still good law: "Physicians are not obligated to provide care to a particular patient unless they have agreed to do so."⁶⁴ However, the "No Duty Rule" does not apply to hospital treatment in many cases -- true emergencies.⁶⁵ Ms. Blevins' remark suggests that there would be no real ethical dilemma where a person was denied medical care for failing to share PHI for treatment or payment purposes. The dilemma centers on the uses and disclosures for health care operations. The reason that she and others within the health care community are concerned with health care operations is not because of some of the activities that make up health care operations, but rather because of its broad definition given to it in the Privacy Rule.

The broad definition of health care operations. The Privacy Rule's definition of health care operations, quoted in section IV, can reasonably be seen as being all-encompassing. The Final Rule's definition includes more activities than in the Proposed Rule,⁶⁶ and these definitional add-ons are most troubling to the health care community. There are two new categories: Business planning and development and Business management and general administrative activities of the entity. The latter category even

⁶² Sue A. Blevins, *supra* note 60.

⁶³ Hurley v. Eddingfield, 59 N.E. 1058 (Ind. 1901)

⁶⁴ William J. Curran, Mark A. Hall, Mary Anne Bobinski, David Orentlicher, Health Care Law and Ethics, 5th Edition, Aspen Law & Business, 1998, p. 128.

⁶⁵ *Id.* at 134.

⁶⁶ Final Privacy Rule Preamble, Part I, *supra* note 38, at 32.

includes fundraising (for the benefit of the covered entity) and marketing activities (of certain services to individuals served by the covered entity).⁶⁷

Several organizations within the health care community voiced specific concern on the effect that the definition of health care operations would have on patients' "voluntarily" consenting to the use of their PHI. One such organization, the AMA, stated in its testimony before the Subcommittee that a broad definition of health care operations that included what it termed, non-routine, non-critical activities will have the effect of coercing patients to consent to uses and disclosures of their PHI for many activities that should be optional.⁶⁸ Looked at from the patient's perspective, in order to get the medical care needed for a given ailment, the patient not only needs to consent to the medically necessary uses and disclosures of his or her PHI, but, if he or she really wants to receive treatment, he or she will also have to consent to other uses and disclosures of the PHI that have no bearing on his or her medical care, such as fundraising and marketing activities.

The Institute for Health Freedom introduced another concern centering on the broad definition of health care operations -- the possible loss of protection for PHI that goes to third parties. Several health care operation activities will be undertaken by third parties. The Preamble to the Final Rule specifically states, "Disclosures for health care operations may be made to an entity that is neither a covered entity nor a business associate of the covered entity."⁶⁹ This is troubling because, as stated in the Final Rule, "Once protected health information leaves a covered entity the Department [HHS] no

⁶⁷ Id.

⁶⁸ Jacqueline M. Darrah, MA, JD, "Consent Issues in Implementation of the 'Standards for Privacy of Individually Identifiable Information'." National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality. Washington D.C. 21 Aug. 2001. 24 Sep 2001

<http://www.ncvhs.hhs.gov/0100821p6.htm>.

⁶⁹ Final Privacy Rule Preamble, Part I, *supra* note 38, at 33.

longer has jurisdiction under the statute to apply protections to the information."⁷⁰ Therefore, not only does the Final Rule mandate that patients consent to uses and disclosures of their PHI for purposes to include health care operations in order to receive their medical care, it is mandating that they consent to blindly letting their PHI go to third parties whom the DHHS has no jurisdiction over and, thus, cannot protect their information.

The administrative burden of the consent requirement. When patients seek medical care, they reasonably expect that their PHI will be used for legitimate purposes to further their medical care. Mr. Bruce Kelly, Director of Government Relations for Mayo Foundation, in his testimony before the Subcommittee for Privacy and Confidentiality, listed some reasonable patient expectations for the use and disclosure of their PHI:

- Patients who seek treatment expect that their treatment will be based on accurate and complete information, available to all the professionals involved in their treatment.
- Patients expect that their health care provider will rely on patient information to receive payment for the medical services delivered.
- Patients expect that patient information will be used by providers to fulfill their obligations to provide quality care and assure patient and employee safety.⁷¹

Mr. Kelly further stated that requiring prior consent for the use and disclosure of PHI will do nothing to change these expectations. The only sure result of the consent requirement is the creation of additional "nuisance" paperwork and create problems for

⁷⁰ Sue A. Blevins, *supra* note 60, at 4.

⁷¹ Bruce Kelly, Testimony, National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality, Washington D.C., 21 Aug. 2001. 24 Sep. 2001
<http://www.ncvhs.hhs.gov/010821p3.htm>.

conscientious health care providers.⁷² The Healthcare Leadership Council, in a letter to Secretary Tommy G. Thompson, HSS, wrote, "Adding yet another mandatory form to the already unmanageable paperwork burden that physicians and practitioners face on a daily basis does not effectively achieve the shared goals of health care providers and HHS to provide patient privacy protection and access to health care."⁷³ The Council further used Secretary Thompson's own words to support this sentiment, "Over-regulation undermines quality of care and health care delivery by using scarce resources unproductively. We can help improve patient care by bringing more common sense into the regulatory process...We need to act quickly when there are problems with our regulations."⁷⁴

Several organizations in the health care community voiced concerns about the effects of the administrative burdens of the consent requirement on patient care and quality assurance. The APhA in its testimony before the Subcommittee voiced concern about the consent requirement creating an administrative and financial burden that will adversely affect patient care.⁷⁵ The consent requirement erects significant barriers to the quick, efficient, and safe delivery of health care that patients count on pharmacists to provide. APhA testimony used language from the Proposed rule, which lacked the consent requirement, to show the ill effects of the consent requirement, "According to the proposed rule, prior consent is unworkable, unrealistic, and would not provide meaningful privacy protection."⁷⁶ A delay created by the consent requirement can cause patient inconvenience and delay access to necessary treatment. For example, "A mother

⁷² Id.

⁷³ Healthcare Leadership Council, Letter to Secretary Tommy G. Thompson, U.S. Department of Health and Human Services, 8 Feb. 2002. 23 Feb. 2002 <http://www.hlc.org/html/2-08-02specgrpconst.html>. p. 1.

⁷⁴ Id.

⁷⁵ Ms. Susan C. Winckler, RPh., JD, Director of Policy and Advocacy for the American Pharmaceutical Association, Testimony, National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality, 21 Aug. 2001. 24 Sep. 2001 <http://www.ncvhs.hhs.gov/010821p5.htm>.

⁷⁶ Id. at 2, citing 64 Federal Register at 59,941.

with an ill infant will not be able to pick-up an antibiotic phoned-in by her pediatrician until she arrives at the pharmacy, reads, and completes the consent form."⁷⁷ Kaiser Permanente in its testimony before the Subcommittee spoke of the consent requirement's effect on health care operations. "No health care information in our systems can be lawfully used until consent is obtained; yet we have no practical way to segregate the data for members who have consented from those who have not...All existing data would have to be either blocked or archived."⁷⁸ Kaiser Permanente noted that the consent requirement will, thus, have a detrimental effect on quality review, provider credentialing, planning, evaluation of drugs, and medical devices.⁷⁹

Another concern regarding the administrative burden of the consent requirement is its effect on the physician-patient relationship. The Mayo Foundation believes that the "whole model" of confronting patients when they enter the office with consent requirements is bad medical practice. The current number of patient-completed forms for regulatory purposes is already quite burdensome to patients and providers. It stated, "The increasing demand placed on patients will likely lead to hastily completed forms and potentially inaccurate information that may impair the goal of patient care...This immediate obligation for the patient has a high likelihood of damaging the physician-patient relationship."⁸⁰

Because consent is required for much more than treatment -- activities that involve the use of medical records well past treatment, such as quality reviews and adverse medication notifications, the consent requirement creates a large burden,

⁷⁷ Id. at 2.

⁷⁸ Ms. Mary Henderson, National HIPAA Program Director for Kaiser Permanente, Testimony, National Committee on Vital and Health Statistics Regarding the HIPAA Consent Requirement. p. 3.

⁷⁹ Id.

⁸⁰ Bruce Kelly, *supra* note 71, at 3.

especially for the larger organizations, to obtain consents from not only those patients who are currently receiving treatment, but also, arguably, from all former patients as well. Kaiser Permanente has 8.2 million current members and over 35 million former members who, under the consent requirement will need to provide consent in order for Kaiser Permanente to use their PHI after April 14, 2003.⁸¹ The administrative burden of just finding the members and former members, some who have moved, some who have married and changed names, and some who have died is mind-boggling. Once such individuals are found, there is then the burden of obtaining the consent, via mail most likely, with the predictable low return rate. Kaiser Permanente stated that, even for the patients coming in for care, there will be a significant burden. Given the managed care environment, physician-patient appointment times are already critically short. Given the number of its members, adding just one minute for consent to the Kaiser Permanente medical office visit, which seems quite optimistic, will significantly increase staff workload and patient wait times. As an example, "Kaiser Permanente providers in California deliver care for approximately 25 million member visits per year, and a minute added to each visit registration would roughly equal 420,000 hours of new staff workload that would need to be supported in California alone."⁸²

The effects of revocation of consent. "Upon receipt of the written revocation, the covered entity must stop processing the information for use or disclosure, except to the extent that it has taken action in reliance on the consent."⁸³ While revocation of consent will likely lead to the termination of any treatment, its effects will be greatest in areas

⁸¹ Ms. Mary Henderson, *supra* note 78, at 2.

⁸² *Id.* at 6.

⁸³ Final Rule Preamble II, *supra* note 36, at 70.

such as notifications for adverse medication reactions, quality reviews, and health statistics.

The APhA is very concerned with the effects of revocation of consent. According to APhA, in situations such as the identification of a contaminated, counterfeit, or ineffective product, urgent notification of the patient(s) is required. For example, "pharmacists use individually identifiable information to contact patients who have received a specific medication that is the subject of a recall by the Food and Drug Administration (FDA)."⁸⁴ Under the Final Rule, a pharmacist would not be able to contact and, thus, warn any patients who may have revoked their consent. In the last year there was a very serious case where patients may have received an over-diluted chemotherapy medication.⁸⁵ Those potentially affected patients needed to be notified immediately. Revocation of consent, in that case, could likely have caused unneeded loss of life. APhA stated that situations such as the above one may fit the exception for emergency situations, but further stated, "Any hesitation caused by concern for compliance with this regulation is unacceptable -- but such hesitation could occur."⁸⁶

Hospitals and health plans use medical records to perform quality assessments and peer review. Revocation of consent would render that patient's medical records off limits to review, and thus any lessons learned from that patient's care would be lost. The Mayo Foundation noted that a patient who was unhappy with a medical outcome may be the most likely to revoke consent. Therefore, the cases that would be of greatest benefit

⁸⁴ Ms. Susan C. Winckler, *supra* note 75, at 2.

⁸⁵ *Id.*

⁸⁶ *Id.*

to review for peer review and quality assurance purposes, may be the cases where access to PHI has been revoked.⁸⁷

The NCQA voiced concern about the effects revocation of consent would have on the health plans' ability to perform key functions. It testified before the Subcommittee on Privacy and Confidentiality that prohibiting health care providers from disclosing an individual's PHI would adversely impact their ability to perform quality and utilization reviews.⁸⁸ NCQA believes that this would result in limiting health plans to merely performing finance and insurance functions. They would, therefore, lose their unique capacity to "marshal" their considerable resources in advancing quality health care.⁸⁹

Another area where access to medical records is essential is in the compilation of health statistics. Such statistics play a vital role in assessing the requirements of future medical services and in assessing the incidence rate of diseases. Kaiser Permanente noted that, in order to provide Medicare services, it is necessary to use data from the past four to five years to plan for upcoming coverage years. "It is essential for continuing and future members for the plan to use that information to determine what kind of facilities are likely to be necessary, what kinds of diseases and treatments need to be considered, and the number and kinds of physicians and other health care providers to whom members will need access."⁹⁰ Incidence rates, cure rates, and other vital statistics are routinely gathered on a myriad of diseases to assess public health threats and advancements. Such statistics are vital in assessing health risks as well as prognoses for

⁸⁷ Bruce Kelly, *supra* note 71, at 3.

⁸⁸ Sharon King Donohue, General Counsel of the National Committee for Quality Assurance, Testimony, National Committee for Quality Assurance, Subcommittee on Privacy and Confidentiality, 21 Aug. 2001. 24 Sep. 2001 <http://www.ncvhs.hhs.gov/010821p2.htm>, p. 4.

⁸⁹ *Id.*

⁹⁰ Susan Winckler, *supra* note 75, at 8.

certain diseases. Revocation of consent could wreak havoc with these statistics. Records for which there has been a revocation of consent cannot be used in statistical data; therefore, the accuracy of the statistics will be adversely affected. Inaccurate statistics could then lead to misallocations of resources for future medical services, causing health care costs to further escalate.

Other concerns. One of the stated goals of HIPAA Administrative Simplification is to improve the efficiency and effectiveness of the health care system by encouraging the development of electronic health information systems. Ironically, according to Kaiser Permanente, the consent requirement is likely to be easiest to administer by a single-site health care provider that uses paper records. For larger organizations, such as health care systems, who have multiple sites, the process of obtaining the consent, storing it, tracking it, and updating its status will be very onerous.⁹¹

Finally, health care providers feel they will be placed in an untenable position by the consent requirement. "The right of a provider to condition treatment upon the patient giving written consent is often meaningless within the ethical practice of medicine. In many circumstances, the health care provider is under an ethical obligation, and often a legal obligation, to render the proper care when necessary, even if a patient refuses to sign a form."⁹² In a situation where a patient revokes consent during hospitalization, the health care provider would be ethically and legally obligated to continue treatment; however, in order to comply with the Privacy Rule, he or she would have to do so without the aid of the patient's PHI (medical record).⁹³

⁹¹ Mary Henderson, *supra* note 78, at 2.

⁹² Bruce Kelly, *supra* note 71, at 2.

⁹³ *Id.*

B. Consent Requirement Recommendations

The organizations in the health care community did, indeed, make their concerns known to the Subcommittee; however, they went a significant step further by providing the Subcommittee a myriad of recommendations on how to improve the Privacy Rule as it pertains to the consent requirement. The recommendations ranged from complete deletion of the consent requirement to several alternatives for modifying the consent requirement, including the changing of key definitions, restricting the consent requirement to routine and necessary purposes, and restricting the consent requirement to uses other than routine or necessary purposes.

Deletion of consent requirement. It is reasonable to assume that, when a person seeks medical care, he or she understands that his or her PHI will be necessary for TPO, especially for treatment and payment purposes. With this assumption in mind, several organizations recommended complete deletion of the consent requirement from the Privacy Rule. Each organization gave its own rationale for recommending deletion of the consent requirement.

The Mayo Foundation recommended that the consent requirement be deleted from the Privacy Rule essentially because patients reasonably expect their PHI to be used for TPO purposes. In contrast, Kaiser Permanente recommended deletion of the consent requirement because it is coercive. Its conclusion was aided by HHS's stated purpose for not putting the consent requirement into Proposed Rule, "In the NPRM, we expressed concern about the coercive nature of consents currently obtained by providers and plans relating to the use and disclosure of health information."⁹⁴ Though HHS put the consent requirement in the Final Rule, it again stated concern about the coercive nature of the

⁹⁴ Final Privacy Rule, Preamble, Part I, supra note 38, at 27.

consent requirements.⁹⁵ It also reasoned that the consent requirement could be deleted because the Final Rule already provided other meaningful tools that will serve to protect an individual's medical privacy.⁹⁶

The NCQA, concerned that the consent requirement at the provider level may obstruct health plan access to information needed to support vital quality of care measures, recommended that the original provisions of the Proposed Rule be adopted. This would allow health care providers to use and disclose PHI for TPO without having to obtain consent. NCQA emphasized that the notice requirement should be maintained.⁹⁷ The notice requirement will ensure that individuals are apprised of the uses and disclosures of their PHI, while avoiding the administrative burden of the consent requirement. The Healthcare Leadership Council joined the NCQA in this recommendation.⁹⁸

The APhA also recommended adoption of the Proposed Rule's provisions. This would help health care providers and patients to better distinguish between activities that could be undertaken without any consent (TPO) and other activities requiring written authorization, such as fundraising.⁹⁹

⁹⁵ Id. "While our concern about the coerced nature of these consents remains, many comments that we received from individuals, health care professionals, and organizations that represent them indicated that both patients and practitioners believe that patient consent is an important part of the current health care system and should be retained."

⁹⁶ Mary Henderson, *supra* note 78, at 2. The other tools are: 1) precise limits on the allowable uses and disclosures of PHI; 2) a notice provision; 3) specific written authorizations for other uses outside of TPO; and 4) sanctions for misuse of PHI.

⁹⁷ Sharon King Donohue, *supra* note 88, at 4.

⁹⁸ Healthcare Leadership Council, Letter to Secretary Tommy G. Thompson, U.S. Department of Health and Human Services, 8 Feb. 2002. 23 Feb 2001 <http://www.hlc.org/html/2-08-02specgrpconst.html>.

⁹⁹ Susan C. Winckler, *supra* note 75, at 5.

Modifications to the Consent Requirement. In lieu of deleting the entire consent requirement from the Privacy Rule, several organizations recommended modifications that would alleviate their concerns with the consent requirement.

The AMA strongly recommended narrowing the definition of health care operations. The definition should be narrowed to include only routine and necessary purposes. The AMA believes that it would be appropriate for health care providers to condition medical treatment or for health plans to condition enrollment on the patient's consent to use or disclosure of PHI, but only as it relates to TPO with the narrow definition of health care operations.¹⁰⁰ The AMA recommends that authorization, in lieu of consent, be required for non-critical, non-routine uses and disclosures of PHI. The narrowing of the definition of health care operations is critical, especially in the event that the consent requirement is deleted in its entirety.¹⁰¹ Otherwise, in the event authorization requirements were not modified to include the non-routine, non-critical uses and disclosures, an individual's PHI will be freely subject to uses and disclosures by health care providers, health plans, and even third parties for purposes beyond that reasonably contemplated by an individual.

The Mayo Foundation, as an alternative to deleting the consent requirement, recommended that "Records created before implementation of this rule should be exempt from the consent requirement until a patient encounter occurs after the implementation of this rule."¹⁰² The alternative recommendation would greatly lessen the administrative burden of locating and contacting an organization's entire patient population, which was a great concern for larger organizations.

¹⁰⁰ Jacqueline M. Darrah, *supra* note 68, at 4.

¹⁰¹ *Id.*

¹⁰² Bruce Kelly, *supra* note 71, at 2.

Kaiser Permanent, as an alternative to the complete deletion of the consent requirement, recommended seven measures to aid in lessening the negative impact of the HIPAA consent requirement:

- Allow continued use of the data collected before the April 14, 2003 compliance deadline and require consent only for data collected after that date.
- Allow use and disclosure of data collected before revocation for continuing TPO.
- Allow the continued use of data until a patient makes a physical appearance and is able to sign a consent form.
- Make the HIPAA consent requirement inapplicable to states that have statutory authorization for the use and disclosure of PHI.
- Defer the consent requirement for five years. Then assess whether the other HIPAA tools provide adequate protection.
- Reconcile conflicting laws, such as those that do not permit disenrollment upon the revocation of consent.
- Rely on parental consent for a child who reaches the age of majority until that new adult comes in for care.¹⁰³

Kaiser Permanente's alternatives would lessen the administrative burden of the consent requirement as well as the effects of revocation. Specifically, they would allow for the continued use of PHI whose uses and disclosures had either been consented to or had been used and disclosed prior to the compliance date of the Privacy Rule. This would allow for uninterrupted care, and would allow health plans to continue to obtain the needed information for quality and utilization reviews.

The APhA, as an alternative to deleting the consent requirement, recommended several possible modifications. First, it recommended that the Rule be modified so that the very act of presenting a prescription to the pharmacy (in person or via telephone or

¹⁰³ Id. at 3,4.

computer) qualifies as implied consent.¹⁰⁴ This recommendation would serve to alleviate the administrative burden of obtaining consent and any adverse effects that the consent requirement (either in its attainment or in its revocation) would have on patient care and notification of adverse medication incidences. It next recommended that the word, "prior" be deleted from the consent requirement. This would not alleviate the administrative burden of the consent requirement, but it would minimize any disruptions in the provision of health care. APhA also recommended allowing one consent form to cover all TPO for any and all covered entities.¹⁰⁵ This modification would serve to reduce the administrative burden of the consent requirement, and would allow for smoother, more efficient medical care. Physicians would be able to disclose information to another physician or pharmacist who, in turn could use the PHI for TPO. Finally, APhA recommended that the compliance date be delayed until two years after the release of the final modifications.¹⁰⁶ HHS has indicated that further modifications would be released, which has created some uncertainty as to what final requirements will be. The recommended delay would allow covered entities sufficient time to ensure compliance with the Rule.

C. Minimum Necessary Standard Concerns

While each organization had concerns from its perspective, looking to them as a whole, their concerns can be grouped into three main categories: the vagueness and ambiguity of the minimum necessary standard; the prejudicial nature of partial information; and the effects the minimum necessary standard may have on quality health care.

¹⁰⁴ Id.

¹⁰⁵ Id.

¹⁰⁶ Id.

The vagueness and ambiguity of the minimum necessary standard. In July 2001 HHS released guidance on the minimum necessary standard which stated that it expected covered entities to exercise "substantial discretion as to how to implement the minimum necessary standard, and appropriately and reasonably limit access to the use of identifiable health information..."¹⁰⁷ The guidance further stated that the standard "requires covered entities to make their own assessment of what PHI is reasonably necessary for a particular purpose, given the characteristics of their business and workforce, and to implement policies and procedures accordingly."¹⁰⁸ As brought out in the guidance, the Minimum Necessary standard does not provide specific steps to follow for adherence; rather, it provides a very general framework and places great discretion on covered entities. HIAA, NCQA, AAHP, and AAPS voiced concerns before the Subcommittee on Privacy and Confidentiality regarding the vagueness and ambiguity of the Minimum Necessary standard.

HIAA testified that, because of the inherent vagueness of the Minimum Necessary standard, there may be defensive restrictions on the flow of PHI between providers and health plans.¹⁰⁹ The flexibility of the standard, according to HIAA, introduces a great deal of uncertainty regarding what measures are necessary in order to comply with the regulation. HIAA fears that with this uncertainty comes legal risk; it is concerned that covered entities, seeking to minimize exposure to liability, will err on the side of being

¹⁰⁷ U.S. Department of Health and Human Services, Office of Civil Rights, "Standards for Privacy of Individually Identifiable Health Information," 6 Jul. 2001, cited in Henry R. Desmarais, MD, MPA, "The 'Minimum Necessary' Standard under the HIPAA Privacy Regulation." National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality, Washington D.C., 22 Aug. 2001, 24 Sep. 2001 <http://www.ncvhs.hhs.gov/010822p1.htm>.

¹⁰⁸ Id., at 3.

¹⁰⁹ Id. at 2.

overly restrictive.¹¹⁰ The resultant diminished availability of information may likely adversely impact the quality and affordability of health care.¹¹¹

NCQA testified that the ambiguity of the standard coupled with the fear of enforcement action will limit the flow of information, which in turn will adversely effect quality assurance measures, disease management, and accreditation.¹¹²

AAHP warns that vagueness and ambiguity of the minimum necessary standard will lead the plaintiff's bar to use the standard as a weapon.¹¹³ It states that covered entity's deliberations will be overshadowed by concern about any enforcement action. This concern is fueled by "the potential for class action litigation, the creativity of the plaintiff's bar in seeking causes of action and the current hostile climate that exists for managed care companies.¹¹⁴

AAPS feels that, because the minimum necessary standard is basically undefined, it is, therefore, unenforceable.¹¹⁵ It states that physicians will be "forced into a game of regulatory roulette, guessing what standard to follow without a final authority or even advisory opinion, while being subject to criminal penalties if they guess wrong."¹¹⁶

The concern about the liability risk due to the vagueness and ambiguity of the Minimum Necessary standard seems to be misplaced. HHS, itself, stated that its intent is for covered entities to exercise "substantial discretion" in the implementation of this

¹¹⁰ Id. at 3.

¹¹¹ Id.

¹¹² Sharon King Donohue, *supra* note 88, at 5.

¹¹³ Kenneth W. Fody, "The 'Minimum Necessary' Use and Disclosure of Protected Health Information", National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality, Washington D.C., 22 Aug. 2001, 24 Sep. 2001 <http://www.ncvhs.hhs.gov/010822p3.htm>.

¹¹⁴ Id.

¹¹⁵ Kathryn Serkes, Testimony, National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality, Washington D.C., 22 Aug. 2001, 24 Sep. 2001

<http://ncvhs.hhs.gov/010822p5.htm>.

¹¹⁶ Id.

standard. It purposefully allows covered entities to make their own assessment of what PHI is needed for a given purpose. HHS does, however, provide a framework to, perhaps, guide a covered entity in its assessment of what is reasonably necessary. The Preamble provides the following reasonableness factors:

- The extent to which the use or disclosure would extend the number of persons with access to the protected health information.
- The likelihood that further uses or disclosures of the protected health information could occur.
- The amount of protected health information that would be used or disclosed.
- The importance of the use or disclosure.
- The potential to achieve substantially the same purpose with de-identified information.
- The technology available to limit the amount of protected health information used or disclosed.
- The cost of limiting the use or disclosure.
- Any other factors that the covered entity believed were relevant to the determination.¹¹⁷

Because of this, the risk of enforcement action coming directly from HHS appears to be low. Further, there is no private right of action provided for in the Act. However, individuals may have other avenues for redress. In fact, the Privacy Rule provides individuals the right to file a complaint that will initiate an investigation by HHS.¹¹⁸ Additionally, an individual could file suit for medical malpractice for breach of the standards found in the Privacy Rule, although to prevail, he would have to prove breach of the standard within the medical community. Based on the flexibility of the Minimum

¹¹⁷ Final Rule Preamble, Part II, supra note 36.

¹¹⁸ Final Privacy Rule, supra note 18, at 45 CFR § 160.306, 11.

Necessary standard, it would be difficult to ascertain a specific standard in the medical community upon which to base a breach. Therefore, the likelihood of success in the medical malpractice arena also seems low. Although the actual risk of liability may be low, the fact that many in the health care community are concerned about it may likely result in overly cautious limitations on the use and disclosure of medical records.

While the concerns of liability risk may be misplaced, other following concerns based on the vagueness and ambiguity of the Minimum Necessary standard, are better founded.

Misplaced discretion may limit usefulness of information. HIAA feels that the standard inappropriately places the discretion on the covered entity receiving requests for information. It testified that, "Only the entity making a request for information has an informed basis for determining whether the information is the minimum necessary for its purposes" and further stated, "This aspect of the standard almost certainly will lead to inappropriate restrictions on the disclosure of health information."¹¹⁹

AAHP noting the discretion concern stated, "The problem is that the PHI that Covered Entity A needs is not the same PHI that Covered Entity B believes is necessary to perform the same operation."¹²⁰ They further state that the receiving entity is inclined to be conservative since it does not need the information, but would likely be worried about potential liability if the information is later misused.¹²¹ AAHP notes that the Privacy Rule does provide that a covered entity may rely on a request for information from another covered entity if that reliance is reasonable that the information is the

¹¹⁹ U.S. Department of Health and Human Services, *supra* note 107, at 3.

¹²⁰ Kenneth W. Fody, *supra* note 113, at 3.

¹²¹ *Id.*

minimum necessary for the stated purpose. However, it points out that the Privacy Rule leaves room for entities to disagree over reasonableness of the request.¹²²

Minimum necessary standard may be used to shield information. HIAA testified that it is concerned that the minimum necessary standard may be used to shield "wasteful, abusive, and fraudulent activities."¹²³ Because of the subjectivity of the standard, it will be easy for "bad actors" to use the standard to justify withholding information that would provide evidence of "upcoding, misdiagnosis, over-treatment, or outright fraud."¹²⁴ HIAA noted that the General Accounting Office (GAO) has estimated that as much as ten percent of the nation's expenditure for health care is attributable to fraudulent and/or abusive activities.¹²⁵

Administrative burden of the minimum necessary standard. NCQA testified before the Subcommittee that defining what is the "minimum necessary" for all potential uses and disclosures relevant to certain health care operations will be difficult and administratively burdensome.¹²⁶ It will be especially difficult for health plans performing quality assurance measures to determine what PHI is relevant to a certain task without having access to and reviewing the entire medical record.¹²⁷ As an example, "attempting to appropriately match a plan's disease management program to an enrollee without complete knowledge of the individual's current medical condition and related or secondary illnesses would be impossible."¹²⁸

¹²² Id.

¹²³ Henry R. Desmarais, *supra* note 107, at 3.

¹²⁴ Id.

¹²⁵ Id. at 4.

¹²⁶ Sharon King Donohue, *supra* note 88, at 5.

¹²⁷ Id.

¹²⁸ Id.

A report prepared by the First Consulting Group for the American Hospital Association on the impact of the HIPAA Final Privacy Rule noted that a significant change in the Final Rule from the Proposed Rule is the inclusion of paper-based PHI.¹²⁹ This change greatly expands the "scope of the investigation" necessary to satisfy the minimum standard.¹³⁰

The prejudicial nature of partial information. AAPS warns that the "minimum necessary" information might be just as prejudicial, if not more so, than a person's entire medical record.¹³¹ An example of this prejudicial tendency is, "the presence of a diagnostic code for anxiety or depression could be prejudicial, whereas an understanding of the likely nonrecurring circumstances and the response to treatment would show the patient's generally excellent mental status."¹³² AAPS notes that patients should understand that the minimum necessary standard bears little relationship to the potential harm from disclosure. Rather, information is more likely to be segregated by type than by sensitivity.¹³³ For example, "The very fact that a laboratory test (such as a drug screen) was done may be prejudicial even though the test was negative and was required because of a job requirement not because of suspected drug abuse...The requester of the information may actually have no need to know about it, even though a categorical request for lab tests was made."¹³⁴

¹²⁹ First Consulting Group, Report on the Impacts of the HIPAA Final Privacy Rule on Hospitals, March 2001, 11.

¹³⁰ Id. at 12.

¹³¹ Kathryn Serkes, *supra* note 115, at 3.

¹³² Id.

¹³³ Id. at 5.

¹³⁴ Id.

D. Minimum Necessary Standard Recommendations

Based on the above concerns, organizations in the health care community made recommendations for the Minimum Necessary standard ranging from deleting it in its entirety from the Privacy Rule to making various modifications to it.

Deletion of Minimum Necessary Standard. HIAA and the Healthcare Leadership Council both recommend deletion of the Minimum Necessary standard from the Privacy Rule. HIAA made its recommendation before the Subcommittee in August 2001, the Healthcare Leadership Group made its recommendation in a letter to HHS in March 2001.

HIAA recommends deletion of the standard based on its belief that other parts of the Rule adequately protected PHI.¹³⁵ The Privacy Rule, even without the Minimum Necessary standard, contains considerable restrictions on the amount and types of information that can be used and disclosed by covered entities. HIAA believes those restrictions are more susceptible to objective and consistent application by covered entities than the Minimum Necessary standard.¹³⁶ Using a more objective standard will relieve the concerns of vagueness and misplaced discretion. Two elements that serve to protect PHI are the authorization requirement and the notice requirement. A core principle of the Privacy Rule is that a covered entity may not use or disclose PHI for purposes other than TPO, and certain other limited purposes, without first obtaining a written authorization from the individual.¹³⁷ Additionally, the Rule requires that any use

¹³⁵ Henry R. Desmarais, *supra* note 107, at 2.

¹³⁶ *Id.* at 5.

¹³⁷ *Id.*

or disclosure of PHI by a covered entity must be consistent with those provided in the covered entity's notice of privacy practices, which must be provided to each individual.¹³⁸

The Healthcare Leadership Council's recommendation to delete the Minimum Necessary standard is based on its belief that it is unnecessary.¹³⁹ It noted that the Minimum Necessary standard specifically stated that it does not apply to the disclosure of PHI for treatment and that, from this, it can reasonably be implied that the standard does apply to the use of information for treatment purposes. The Healthcare Leadership Council believes the restriction on use is not only unnecessary and a waste of resources, but also potentially dangerous.¹⁴⁰ If HHS intended for uses for treatment to be excluded from the minimum necessary standard as disclosures for treatment are, the Healthcare Leadership Council recommends making that clear in the Rule.¹⁴¹

Modifications to the minimum necessary standard. Each of the modifications recommended by organizations in the health care community attempts to create more certainty and objectivity in the minimum necessary standard with the ultimate aim of reducing the risk of liability.

Mr. Ken Fody, AAHP, to demonstrate the confusion generated by the minimum necessary standard, related this story:

On Monday, April 16, the first business day after Secretary Thompson announced that the privacy rule would be adopted as planned, I learned that a doctor was refusing to allow a team from my company to perform a HEDIS review. The reason: the HIPAA privacy rule prohibited the doctor from releasing the information. I received three more, identical phone calls within the next two weeks. I do not know how many times that situation has repeated since then because I

¹³⁸ Id.

¹³⁹ Healthcare Leadership Council, Letter to U.S. Department of Health and Human Services, 29 Mar. 2001, 3.

¹⁴⁰ Id.

¹⁴¹ Id. at 13.

crafted a standard letter for providers pointing out, among other things, that the privacy rule is not effective for two years. If there is confusion over something as simple as the implementation date, imagine the potential for confusion and conflict when we get to the substance of the rule.¹⁴²

AAHP, therefore, recommended to the Subcommittee on Privacy and Confidentiality, with the aim of making the standard less ambiguous and minimizing liability, that the Privacy Rule be modified to do the following:

- clarify that covered entities may develop broadly worded policies and procedures for categories of operations;
- prevent disputes between covered entities by encouraging a covered entity receiving a request from another covered entity to rely on that request;
- clearly indicate the standard of conduct established for a covered entity and the extent of a covered entity's discretion;
- establish that the minimum necessary requirement does not apply to uses of information that has been obtained from another covered entity;
- clarify that a covered entity's organization, procedures and information infrastructure are factors to be considered in determining what information is necessary, and that covered entity's therefore may develop different policies and procedures for the same types of operations; and
- clearly indicate that a covered entity has satisfied the minimum necessary requirement if it has identified the information that it reasonably believes to be necessary for the task at hand, even if that information is not actually used.¹⁴³

AAPS, in an effort to clarify the standard and reduce any ambiguities, recommended that HHS make a list of circumstances for which the minimum necessary standard applies and those circumstances for which it does not.¹⁴⁴ AAPS also recommended that all requests for PHI should either be for a copy of the medical record

¹⁴² Kenneth W. Fody, *supra* note 113, at 5.

¹⁴³ Id.

¹⁴⁴ Kathryn Serkes, *supra* note 115, at 6.

within certain parameters (date, type of information), or for a specified set of information to be provided from the record.¹⁴⁵ AAPS believes this to be a more workable standard. "It requires no omniscient person fully cognizant of the content of the record, the needs of the requestor, and the mindset of the enforcer."¹⁴⁶ This recommendation would certainly serve to minimize any ambiguities in the minimum necessary standard.

NCQA, in an effort to ensure the free flow of information to health plans for quality enhancing activities, recommended that the minimum necessary standard exempt from its coverage: quality assurance, performance evaluations, accreditation activities, and other similar health care operations.¹⁴⁷ NCQA believes that otherwise, given the ambiguity of the standard, there is no assurance that covered entities will comply with legitimate requests for PHI needed for the continuous improvement of health care.¹⁴⁸

VII. PRIVACY RULE'S EFFECT ON COST & QUALITY OF HEALTH CARE

There are many aspects of the Privacy Rule that will affect the cost and quality of health care. This paper, because of centrality of the two aspects, focused on the Consent requirement and the Minimum Necessary standard. Therefore, the paper only purports to analyze the effects that those two aspects of the Privacy Rule will have on the cost and quality of health care.

A. Effect on the Cost of Health Care

The cost of the entire Privacy Rule was originally estimated by HHS to be between \$1.8 and \$3.6 billion. HHS, however, now estimates the cost of implementation

¹⁴⁵ Id.

¹⁴⁶ Id.

¹⁴⁷ Sharon King Donohue, *supra* note 88, at 5.

¹⁴⁸ Id.

to be approximately \$17.6 billion over ten years.¹⁴⁹ Other estimates, outside HHS, estimate the cost to be \$40 billion over five years.¹⁵⁰

The cost of the consent requirement accounts for only a small portion of the overall costs of the Privacy Rule. HHS estimates a ten year cost of \$227 million; with most of that cost, \$166 million, being attributable to the initial costs of the requirement.¹⁵¹ This estimate may likewise be viewed by those outside of HHS as being optimistically low. HHS, in creating its estimate, projected only a five cent per document cost. Five cents may cover the cost of the paper, and, perhaps, even the ink; but, it does not appear to take into consideration the time associated costs of administering the Consent, both professional and administrative.

The cost of the Minimum Necessary standard, on the other hand, is estimated, by HHS, to be the second costliest aspect of the Privacy Rule. HHS projects the cost to be \$5.8 billion over ten years¹⁵² -- roughly, one third of the entire cost of the Privacy Rule. Other projections put the cost at \$19.8 billion over five years.¹⁵³ In arriving at its estimate, HHS considered that health care providers, hospitals, and health plans will need to establish policies and procedures governing the use and disclosure of PHI, and will, subsequently, have to adjust their practices to conform to the new policies and procedures.¹⁵⁴ The ambiguity of the Minimum Necessary standard may, likely, cause the cost to be closer to the near \$20 billion dollar projection. AAPS flatly stated that it was

¹⁴⁹ John F. Cahill, "Implications of the New Privacy Standards for Healthcare Institutions." Healthcare Financial Management, 6.55 (1 Jun 2001), p. 1.

¹⁵⁰ Id. at 2.

¹⁵¹ Final Rule Preamble, Part IV.

¹⁵² Id.

¹⁵³ Henry R. Desmarais, *supra* note 107, at 5.

¹⁵⁴ Final Rule Preamble, Part IV.

impossible to calculate the cost of applying a standard that is so "vague and ambiguous."¹⁵⁵

The costs associated with these two aspects of the Privacy Rule, as well as the Privacy rule in total, will initially be borne by health care providers, hospitals, and health plans. However, the impact will be on the entire health care community, and will finally be borne by the consumers, through ever higher health insurance premiums.

B. Effect on the Quality of Health Care

One of the purposes of the Privacy Rule, as stated in the Preamble, is to improve the quality of health care by restoring trust in the health care system. There is a fine balance when introducing new regulations into a system between actually improving the system and causing harm to it. Secretary Thompson, as noted in Section VI, recognized this concern when he stated, "Over-regulation undermines quality of care and health care delivery by using scarce resources unproductively." Both the Consent requirement and the Minimum Necessary standard, were introduced to improve the quality of health care; however, the implementation of each will, likely, have an aggregate negative impact on quality.

The Consent requirement was intended to improve the quality of health care through informing patients of how their PHI would be used and disclosed for TPO. Fully informing the patients, it is believed, will secure their trust that their PHI will be protected, and at the very least, ensures they know how their PHI will be handled. As discussed in Section II, trust is essential for quality health care. The patient needs to be able to trust that the health care provider is going to protect his PHI; otherwise, he will

¹⁵⁵ Kathryn Serkes, *supra* note 115, at 4.

not share the more intimate details that may be necessary for effective, quality treatment.¹⁵⁶

While the overall concept of the Consent requirement would, likely, improve the quality of health care, the details of the requirement would, likely, negatively impact the quality of health care. In today's managed care environment, "office-call" time is already at a premium. Adding the requirement of obtaining informed consent will further reduce the time available for treatment. Requiring consent before treatment can be initiated will, likely, cause delay in treatment. The negative impact on treatment is obvious, but the requirement also negatively effects quality by limiting information for health care operations. If an individual either refuses to provide consent or later revokes consent, his PHI will no longer be accessible for the quality review aspects of health care operations. That information would not be available for utilization review, quality assessment review, or for disease management. This lack of information will negatively impact the quality of health care because that information cannot be used as part of the overall assessment for quality review. The individual's own health care may be at risk because of his lack of consent, as well. If there is notification of a medication problem that that individual is taking, if he does not have a Consent, he may not be able to be notified in a timely manner.

The Minimum Necessary standard provides, at least in theory, added trust to individuals that their PHI will not be unnecessarily used or disclosed. It also can improve quality by limiting the opportunities for an individual's medical records to get lost. Limiting uses or disclosures of PHI to the minimum necessary level means that the entire record will not necessarily be continually used for every purpose; rather, only that portion

¹⁵⁶ Final Rule Preamble, Part I, supra note 38.

needed will be used. Therefore, when the medical record is needed for treatment, it is more likely, with this standard, that the records will be available. Having medical records available for treatment is essential for quality care, especially in a case of continuing treatment.

The Minimum Necessary standard may negatively impact quality by limiting information for quality review purposes. Given the concerns over the ambiguous nature of the standard, there may, likely, be cases where information is withheld under the guise of the Minimum Necessary standard. This may, especially, be troubling if the standard is used to wrongly withhold evidence of "bad" care. In such cases, the information that most needs review will not be measured.

While both the Consent requirement and the Minimum Necessary standard have aspects that benefit the quality of health care, both have aspects that can be very detrimental to the quality of health care.

VIII. PROPOSED MODIFICATIONS FROM HHS

"Congress specifically authorized HHS to make appropriate modifications in the first year after the final rule took effect in order to ensure the rule could be properly implemented in the real world."¹⁵⁷ HHS, in fact, in the General Overview of the Privacy Rule announced its intention to issue "proposed modifications to correct any unintended negative effects of the Privacy Rule on health care quality or on access to such care."¹⁵⁸

HHS provided examples of changes they would likely make to the Privacy Rule:

- *Phoned-in Prescriptions* - A change will permit pharmacists to fill prescriptions phoned in by a patient's doctor before obtaining the patient's written consent.

¹⁵⁷ Office for Civil Rights, OCR HIPAA Privacy TA 164.000.001 General Overview, 24 Sep 2001 <http://www.hhs.gov/ocr/hipaa/genoverview.html>. p. 4.

¹⁵⁸ Id. at 3.

- *Referral Appointments* - A change will permit direct treatment providers receiving a first time patient referral to schedule appointments, surgery, or other procedures before obtaining the patient's signed consent.
- *Allowable Communications* - A change will increase the confidence of covered entities that they are free to engage in whatever communications are required for quick, effective, high quality health care, including routine oral communications with family members, treatment discussions with staff involved in coordination of patient care, and using patient names to locate them in waiting areas.
- *Minimum Necessary Scope* - A change will increase covered entities' confidence that certain common practices, such as use of sign-up sheets and X-ray lightboards, and maintenance of patient medical charts at bedside, are not prohibited under the rule.¹⁵⁹

On March 27, 2002, HHS published, in the Federal Register, proposed modifications to the Privacy Rule. Some of the proposed modifications directly impact the Consent requirement and the Minimum Necessary standard. HHS based its proposed modifications on comments it received on the Final Privacy Rule, as well as the testimony provided to and recommendations from the Subcommittee. HHS noted concern by the many comments it received about unintended consequences of the Consent requirement that impede the provision of quality health care.¹⁶⁰

HHS proposed the following modification to the Consent requirement:

The Department proposes to make optional the obtaining of consent to use and disclose protected health information for treatment, payment, or health care operations on the part of all covered entities, including providers with direct treatment relationships. Under this proposal, health care providers with direct treatment relationships with individuals would no longer be required to obtain an individual's consent prior to using and disclosing information about him or her for treatment, payment, and health care operations.¹⁶¹

¹⁵⁹ Id. at 4.

¹⁶⁰ Proposed Modifications to the Privacy Rule, 67 Fed. Reg. 14,780 (Mar. 27 2002).

¹⁶¹ Id.

HHS proposed a modification directly in line with what it proposed in the General Overview:

The Department proposes to modify the Privacy Rule to add a new provision...which explicitly permits certain incidental uses and disclosures that occur as a result of an otherwise permitted use or disclosure under the Privacy Rule. An incidental use or disclosure would be a secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and that occurs as a by-product of an otherwise permitted use or disclosure under the Privacy Rule. The Department proposes that an incidental use or disclosure be permissible only to the extent that the covered entity has applied reasonable safeguards...¹⁶²

IX. RECOMMENDATIONS

My recommendations for modifications to the Privacy Rule pertain only to the two aspects of the Rule that I examined, the Consent requirement and the Minimum Necessary standard. Four factors drive my recommendations: Patient expectations, the stated purposes of the Privacy Rule, the concerns voiced in testimony before the Subcommittee by representatives of the health care community, and the effects that the two aspects will, likely, have on the cost and quality of health care.

A. Recommendations for the Consent requirement

I recommend completely deleting the Consent requirement from the Privacy Rule. I further recommend that the definition of "health care operations" be narrowed to include only quality review-related activities; thereby deleting from the definition activities such as marketing and fundraising, which do nothing to further the individual's medical care.

My recommendations coincide with the reasonable expectations of patients, as mentioned in Section VI. Patients seeking treatment reasonably expect their PHI to be used for treatment purposes, for payment purposes, as well as for quality assurance

¹⁶² Id. at 14,785.

purposes. It is unnecessary, therefore, to require Consent for TPO, provided, however, that the definition of health care operations is narrowed.

My recommendations also further the three stated purposes of the Privacy Rule, as listed in Section II: "To protect and enhance the rights of consumers...To improve the quality of health care...To improve the efficiency and effectiveness of health care..."

To protect and enhance the rights of consumers. While having the Consent requirement arguably serves to protect and enhance the rights of consumers, deleting it does not adversely impact that purpose. Although, the individual will not be signing a consent, the Notice requirement, which would still be in the Privacy Rule, provides the individual with all the information regarding the uses and disclosures of his PHI for TPO. Additionally, while the Consent requirement is not "legally" coercive, it is not truly voluntary. Therefore, deleting it could be seen as enhancing the rights of consumers, by not putting them in the situation where they feel compelled to provide their consent in order to receive treatment. My proposed narrowing of the definition of "health care operations" adds even more protection to the rights of consumers. Since the Consent requirement would be deleted, it would be essential to narrow the definition of "health care operations" to ensure that an individual's PHI would not be used for inappropriate uses or uses outside their expectations, such as marketing or fundraising.

To improve the quality of health care. My recommendations will enhance the quality of health care. As previously stated, trust between the health care provider and the patient is essential for quality health care. Given my recommendations, that trust can be furthered by limiting the uses of PHI to that which the patient already expects. Because he will not be concerned with other possible uses and disclosures of his PHI, he

will, likely, feel more comfortable about discussing the necessary information for him to receive proper treatment. Additionally, since the Consent requirement would be deleted, there would be no resulting negative effects in the ability to conduct quality reviews in health care since there would be nothing to revoke. Therefore, covered entities can be assured that individuals' PHI will be available for any necessary quality measurements.

To improve the efficiency and effectiveness of healthcare. The efficiency and effectiveness of health care would be enhanced by the deletion of the Consent requirement. Under the Consent requirement, the Consent was needed before initiation of TPO. Therefore, there would, likely, be undue delays in TPO because of either awaiting Consent or because the Consent had been revoked. Additionally, obtaining Consent would, likely, take time away from an already limited appointment time for treatment. Deleting the requirement would, therefore, allow faster access to treatment , as well as more time for treatment; both of which would further the quality of health care.

My recommendations would also alleviate the concerns of the health care community: the coercive nature of the Consent requirement, the administrative burden of the Consent requirement, the broad definition of health care operations, and the effects of revocation of consent. Deleting the Consent requirement completely removes any concern regarding the coercive nature of the requirement, the administrative burden of the requirement, and the effects of revocation. And, narrowing the definition of "health care operations" directly answers the concern regarding its broad definition. My recommendations, additionally, remove all of the underlying concerns within each of the broader concerns.

The coercive nature of the Consent requirement. While deleting the Consent requirement obviously removes the concern regarding its coercive nature, it also removes the underlying concerns voiced by the health care community regarding the coercive nature of the requirement. Without the competing issue of consent for treatment, health care providers will not be placed in a possibly adversarial position to the patient. Deletion also alleviates the ethical Catch 22 concern, where a health care provider feels that he ethically has to provide treatment to the patient, but because the patient did not provide Consent, he cannot safely do so (since he would have to treat the patient without the benefit of the medical record).

The administrative burden of the Consent requirement. Deleting the Consent requirement alleviates the underlying concern of inconvenience and delays to patients that would be present under the Consent requirement. This is particularly important in patients' interactions with pharmacies. Without the requirement, patients will be able to have their prescriptions filled over the telephone or on the internet, without first having to physically go to the pharmacy to complete a Consent. Additionally, patients will be able to have a family member or friend pick up their medications at a pharmacy for them.

The effects of revocation of consent. Deleting the Consent requirement will remove the underlying effects of revocation of Consent. Health care providers will not be faced with the dilemma of having to terminate treatment due to revocation. Pharmacies will not be faced with the situation of not being able to warn patients of a problem with medication. Pharmacies will be able to maintain all medication records, without the burden of having to separate or destroy those for which Consent had been revoked. With all their records, pharmacies will have the assurance that they are able

to notify all their patients who were given a certain medication in a situation where time may be of the essence. Quality assurance measurements and disease management statistics will be more accurate and valuable because all the records will be subject to review. Under the Consent requirement, records for which there was a revocation of Consent could not be used; therefore, the resultant statistics would be of questionable value.

The broad definition of health care operations. Narrowing the definition to include only quality assurance-related purposes provides patients greater control of their PHI. This is especially important with the deletion of the Consent requirement. Patients will be assured that their PHI is only being used for purposes for which they reasonably expected it to be used. While the other activities currently covered in the definition of health care operations may be useful, they are outside the realm of what patients expect. If patients, nonetheless, want their PHI to be used for those activities, they may do so with the added protection of the Authorization that is provided in the Privacy Rule. The Authorization is currently required for ancillary purposes. Putting the activities, other than those for quality assurance measurement, into the category of ancillary purposes, will ensure patients are specifically notified of these other uses, and are provided the opportunity to specifically authorize a given activity.

Deleting the Consent requirement will have a positive effect on the cost and quality of health care. While the cost associated with the Consent was estimated by HHS to be relatively low, it, quite clearly, did not include all cost areas, including time-associated costs. Without the requirement, any costs that would have been associated with the requirement will be saved. The greater impact of deleting the requirement will

be on the effect of the quality of health care. Many of the above-mentioned concerns centered on the effect on quality. Deleting the requirement eliminates those concerns. More time will be available for treatment during the office-visits, and more information will be available for the quality assurance-related activities, both of which will have a positive effect on the quality of health care.

My recommendation is similar to that which HHS recently published. We both recommend removing the mandatory Consent requirement for TPO. However, HHS does not propose narrowing the definition of health care operations. As I mentioned above, the broad definition is troubling as it is in the existing Final Privacy Rule. But, leaving the definition as is, while removing the Consent requirement would have detrimental effects. An existing concern is that patients may feel "coerced" into providing Consent for uses and disclosures that do not further the individual's health care, such as fundraising and marketing. By deleting the Consent requirement and leaving the definition as it is, the "coercive nature" of the Consent is alleviated. However, in its wake is a much more serious problem. Under that situation, the patient either may not be apprised of all the uses and disclosures of his PHI, or may not have any control over those uses, even if they were made known. Under my recommendation, the patient will be fully notified of all uses and disclosures of his PHI, which will be in line with what would reasonably be expected. Additionally, the patient would be informed of other uses or disclosures of his PHI, outside of TPO, which he could Authorize if he so wanted.

B. Recommendations for the Minimum Necessary standard

I recommend modifying the Minimum Necessary standard, making it not apply for all treatment purposes. I would leave the standard in place, however, for payment and

health care operations. Additionally, I would place sole responsibility for establishing what is minimally necessary on the requesting party.

These recommendations align with patient expectations that their PHI will be used for TPO, while ensuring efficient, high-quality medical care and protecting PHI from overexposure. While patients may reasonably expect that their complete medical records need to be readily available for medical treatment, they may not reasonably expect the same for payment or health care purposes. Medical care is expected to be provided in a timely manner and is, thus, viewed as being time sensitive. Payment and health care operations, while arguably time sensitive, do not hold the import of medical care. Additionally, while an entire medical record may, likely, be needed for treatment, it would not typically be needed for payment and health care operations. Rather, information, pertaining to a specific visit or ailment, would, likely, be needed for those purposes.

My recommendations also further the stated purposes of the Privacy Rule:

To protect and enhance the rights of consumers. Allowing the complete medical record to be available for all treatment purposes, while limiting access for payment and health care operations, certainly protects and enhances the rights of consumers. Ensuring a patient's medical records are available for all treatment purposes, will allow for efficient, quality care. The medical records will not be subject to "subjective" standards regarding what may be needed for a given office visit or ailment. Rather, the entire medical record will be available to the health care provider, who may use it, in toto, to provide complete medical care. Limiting access to the PHI for payment and health care operations protects patients rights because it will control the unnecessary or inappropriate

use of that information. Additionally, limiting access to uses outside the treatment realm increases the likelihood that the entire medical record will be available for medical treatment when it is needed.

To improve the quality of health care. Having the entire medical record available for all medical care is essential for quality care. Having the Minimum Necessary standard not apply to treatment will greatly increase the availability of the entire record for treatment purposes. Quality care is also effected, however, by measurement activities which are part of health care operations. While the Minimum Necessary standard would still apply to health care operations, my recommendation to shift sole responsibility for determining what is minimally necessary on the requester will also enhance quality care. The individuals or organizations who would be performing the quality assessments are in a better position to know what "type" of information is needed in order to perform their assessments. Giving them sole responsibility, and alleviating the responsibility on the provider of the information, should enhance quality by ensuring that they have the information to measure it, and thus make recommendations for improvements.

To improve the efficiency and effectiveness of health care. My recommendations will increase the efficiency and effectiveness of health care over what the Privacy Rule provides. Having the standard not apply for treatment purposes, should provide for faster and complete access to PHI. Since each record will not have to be reviewed, segregated, and sorted out, the records should be available for treatment without delay. Additionally, since the entire record will be available, and not sorted by what has been "subjectively" determined to be minimally necessary, the effectiveness of treatment should be enhanced. Health care providers with the entire medical record, will have access to the patient's

entire medical history which may, in some way, effect the patient's current ailment and treatment.

My recommendations answer the concerns voiced by the health care community: vagueness and ambiguity of the Minimum Necessary standard; misplaced discretion may limit usefulness of information; the Minimum Necessary standard may be used to shield information; the administrative burden of the Minimum Necessary standard; and the prejudicial nature of partial information.

My recommendation to shift sole responsibility for determining what is minimally necessary for a given purpose on the requestor alleviates most of these concerns. HHS has, quite clearly, stated that it intends for covered entities to use their professional judgment on what is minimally necessary. From this, it can be reasonably assumed, that it places confidence in covered entities, and will, thus, not place unreasonable expectations for compliance. Because of this, the concerns regarding the vagueness and ambiguity of the standard, the misplacement of the discretion, and the shielding of information should be answered. The requestor, who needs the information, no longer need worry that the entity supplying the information will use its "subjective" standard for determining what is minimally necessary. Rather, the requester has sole discretion, and the supplier of the information must rely on the request. Not only would the supplier no longer have discretion, it, also, would no longer be subject to enforcement action regarding the Minimum Necessary standard. Therefore, the supplier of the information would have no reason to provide limited information for fear of enforcement action, nor would it have any ability to shield information that it did not want known for quality purposes.

Having the Minimum Necessary standard not apply for treatment purposes should greatly reduce the administrative burden of the standard, as well as reduce the concern about the prejudicial nature of partial information. My recommendation should greatly reduce the administrative burden since no medical record would have to be reviewed prior to any treatment. Even though the standard would still apply for payment and health care purposes, the administrative burden should be lessened there as well. Entities needing information for payment and health care purposes should be in a better position than entities needing information for treatment purposes to use "routine request" formulae, rather than rely on case-by-case analysis. Using "routine request" formulae will be less burdensome for both the requestor and the supplier of PHI. The requestor will not have to make a case-by-case determination, and the supplier of the PHI will know what is routinely needed, and will be able to systematically separate the PHI for those purposes, rather than have to separate information on a case-by-case basis.

My recommendations should have a great impact on the cost and quality of health care. The Minimum Necessary standard is, currently, the second most expensive aspect of the Privacy Rule, estimated at \$5.8 billion over ten years. By making the standard not apply to all treatment purposes, the cost should be greatly reduced. Quality of health care should be enhanced since the entire medical record should be available for all treatment purposes. Placing sole discretion on the requestor for determining what is minimally necessary should ensure that the needed information will be available for the necessary quality assessment reviews. Strengthening the quality assessment review process, should, thus, directly impact the future quality of health care.

My recommendations also remove the inconsistency inherent in the Final Privacy Rule. In the Final Privacy Rule, the standard does not apply to "external" requests for treatment purposes. Therefore, the only treatment purposes the standard applies to are ones internal to the entity. It seems logical that an entity would have greater knowledge and trust in its internal matters than it would have in other entities' matters. Placing the burden on internal uses, while having none for external uses, runs directly against common sense. My recommendation provides consistency for all treatment purposes by allowing the entire medical record to be available for any and all treatment purposes.

While HHS's proposed recommendation for the Minimum Necessary standard, allowing for incidental uses and disclosures of PHI, is an improvement over the current standard, it does not adequately respond to the concerns voiced by the health care industry. My recommendations, not only answer the concerns of the health care industry, they align with patient expectations, further the purposes of the Privacy Rule, and will have a positive effect on the cost and quality of health care.

X. CONCLUSION

The intentions behind the establishment of the Privacy Rule, as evidenced in the Rule's stated purposes of enhancing consumer rights, and improving the quality and efficiency of health care are laudable. And the Privacy Rule, in its present form does much to meet the intentions. However, certain aspects of the Privacy Rule may do more to hinder consumer rights and the quality of health care, than they do to improve them. HHS stated they were open to modifications to improve the Privacy Rule, and, in fact, have made some. Their recent modifications, while an improvement, do not quiet the concerns of the health care community.

My recommendations to the Privacy Rule strengthen the rule by addressing two key aspects of the Rule, the Consent requirement and the Minimum Necessary standard. My recommendations not only strengthen the Privacy Rule and alleviate the concerns of the health care industry, they also will have a positive impact on the cost and quality of health care.

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